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NATIONAL COUNCIL ON DISABILITY

5 CFR Chapter C

RIN 3480–AA00

Freedom of Information Act, Privacy Act, and Government in the Sunshine Act Procedures

AGENCY: National Council on Disability.

ACTION: Final rule.

SUMMARY: The National Council on Disability is finalizing regulations which implement the Freedom of Information Act, the Privacy Act of 1974, and the Government in the Sunshine Act. This rule describes the procedures for members of the public to request access to records. In addition, this document also describes procedures for the Council's responses to these requests, including the timeframe for response and applicable fees. These rules should be read in conjunction with the text of the Freedom of Information Act, the Privacy Act of 1974, the Government in the Sunshine Act, and the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget.

DATES: Effective September 16, 2015.

FOR FURTHER INFORMATION CONTACT: Joan Durocher, General Counsel, National Council on Disability, at 202–272–2004 or *jdurocher@ncd.gov*. To ensure proper handling, please include the docket number on your correspondence.

SUPPLEMENTARY INFORMATION: These regulations in a proposed rule were published for public comment in the **Federal Register** on June 11, 2015 (80 FR 33199), the comment period ended on August 10, 2015, and one commenter provided input. He is a private citizen and submitted his comments by mail.

I. Background

The commenter provided various comments on the proposed Freedom of Information Act procedures at part 10000. First, the commenter recommended that § 10000.6(b) should state that responses to a FOIA request should include the case number and the date of the original request. Reasoning that the absence of this information can cause confusion and wasted effort should an administrative appeal be necessary. We agree with the suggestion and § 10000.6(b) has been modified to reflect that correspondence responding to FOIA requests should include the case number and date of the original request.

In addition, the commenter had several comments about the proposed § 10000.10 concerning fees. The commenter stated that a page duplication fee of $.10 per page should be identified. The commenter states that the fee is supposed to be a proxy based on actual duplication costs. The commenter states actual duplication costs are substantially less than $.10 per page, but the standard rate for most agencies is $.10. FOIA regulation 5 U.S.C. 552(a)(4)(A)(ii) states fees shall be limited to reasonable standard charges for document search, duplication, and review. No specific fee scale was applied in the regulation, the Council does not intend to cite a specific cost for duplication. Not having specific rates listed in the regulation allows the Council to adjust costs accordingly when a price fluctuation exists which allows the Council flexibility to adjust rates without first necessitating a change in the regulation.

In addition, the commenter states in § 10000.10(c) the reference to the operating costs for a central processing unit is obsolete as well as the reference to the salary of the operators performing the search. FOIA regulation 28 CFR 16.10(a)(2) defines direct costs as expenses that an agency incurs in searching for and duplicating (and, in the case of commercial use requests, reviewing) records in order to respond to a FOIA request. For example, direct costs include the salary of the employee performing the work (*i.e.,* the basic rate of pay for the employee, plus 16 percent of that rate to cover benefits) and the cost of operating computers and other electronic equipment, such as photocopiers and scanners. The Council did not find it necessary to make changes to the section, the Council will adhere to all applicable statutes when assessing direct costs.

The commenter states in § 100000.10(d) the rules are ambiguous and should clearly state unambiguously that noncommercial requesters are not charged review fees. The commenter added that OMB guidance is quite clear that noncommercial requesters are not charged. The commenter also stated charging review fees following the results of an appeal in which the written initial determination was reversed or remanded is procedurally unfair and could impose needless hurdles. Council maintains there is sufficient clarity in the current language ''review fees shall be charged for requesters who make commercial use requests''. As to the assessment of review fees post an appeal, Council followed OMB guidelines when proposing review fees be assessed. We appreciate the commenter's perspective, the Council has decided to retain the language which mirrors the FOIA statute. Such fees are allowable under the FOIA regulations and therefore current language will remain unchanged.

Additionally, in § 10000.10(e) the commenter suggests changing the wording of ''statutory entitlements of 100 pages of duplication . . .'' To ''statutory entitlements of 100 pages of duplication or equivalent'', so that other types of duplicated media can be accommodated. With the ever-changing nature in which data is collected the Council agrees with the commenter and will add specific language to the final rule indicating that duplication costs equivalent of 100 pages in print or equivalent will be processed at no charge.

II. Regulatory Analysis and Notices

Executive Order 12866

This final rule is not a ''significant regulatory action'' within the meaning of Executive Order 12866. The economic impact of these regulations should be minimal, therefore, further economic evaluation is not necessary.

Regulatory Flexibility Act, as Amended

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Act of 1996 (5 U.S.C. 601 *et seq.*), generally requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking under the

Administrative Procedure Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a number of small entities. Small entities include small businesses, small organizations, and small government jurisdictions. The Council considered the effects on this final rule on small entities and certifies that these final rules will not have a significant impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, requires each agency to assess the effects of its regulatory actions on state, local, and tribal governments, and the private sector. Agencies must prepare a written statement of economic and regulatory alternatives anytime a proposed or final rule imposes a new or additional enforceable duty on any state, local, or tribal government or the private sector that causes those entities to spend, in aggregate, $100 million or more (adjusted for inflation) in any one year (defined in UMRA as a ''federal mandate''). The Council determined that such a written statement is not required in connection with these final rules because they will not impose a federal mandate, as defined in UMRA.

National Environmental Policy Act

The Council analyzed this action for purposes of the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.,* and determined that it would not significantly affect the environment; therefore, an environmental impact statement is not required.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. This final rule does not include an information collection for purposes of the PRA.

Executive Order 13132 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999, and the Council determined that it does not have sufficient implications for federalism to warrant the preparation of a Federalism Assessment.

List of Subjects

5 CFR Part 10000

Administrative practice and procedure, Freedom of information, Confidential business information, Privacy.

5 CFR Part 10001

Administrative practice and procedure, Privacy.

5 CFR Part 10002

Administrative practice and procedure, Public availability of information, Meetings.

In consideration of the foregoing, the Council amends title 5, Code of Federal Regulations, by establishing chapter C, consisting of parts 10000–10049, to read as follows:

Chapter C—National Council On Disability

PART 10000—PROCEDURES FOR DISCLOSURE OF RECORDS UNDER THE FREEDOM OF INFORMATION ACT

PART 10001—IMPLEMENTATION OF THE PRIVACY ACT OF 1974

PART 10002—IMPLEMENTATION OF THE GOVERNMENT IN THE SUNSHINE ACT

PARTS 10003–10049 [RESERVED]

PART 10000—PROCEDURES FOR DISCLOSURE OF RECORDS UNDER THE FREEDOM OF INFORMATION ACT

Sec.

Authority: 5 U.S.C. 552, as amended; E.O. 12600, 52 FR 23781, 3 CFR 1987, 1987 Comp., p. 235; 3 CFR 235.

§ 10000.1 Purpose and scope.

The regulations in this part implement the provisions of the FOIA.

§ 10000.2 Definitions.

The following definitions apply to this part:

Chairperson means the Chairperson of the Council, as appointed by the President, or any person to whom the Council has delegated authority for the matter concerned.

Chief FOIA Officer means the senior official to whom the Council delegated responsibility for efficient and appropriate compliance with the FOIA, currently delegated to the General Counsel.

Commercial use request means a FOIA request from or on behalf of a requester that seeks information for a use or purpose that furthers their commercial, trade, or profit interests, including pursuit of those interests through litigation.

Confidential business information means trade secrets or confidential or privileged commercial or financial information submitted to the Council by a person that may be protected from disclosure under Exemption 4 of the FOIA.

Council means the National Council on Disability, established by the Rehabilitation Act of 1973 (29 U.S.C. 780 *et seq.*), as amended, and amended by the Workforce Innovation and Opportunity Act (Pub. L. 113–128) in 2014.

Direct costs are those expenses that an agency incurs in searching for and duplicating (and, in the case of commercial use requests, reviewing) records in order to respond to a FOIA request. For example, direct costs include the salary of the employee performing the work (*i.e.,* the basic rate of pay for the employee, plus 16 percent of that rate to cover benefits) and the cost of operating computers and other electronic equipment, such as photocopiers and scanners. Direct costs do not include overhead expenses such as the costs of space, and of heating or lighting a facility.

Educational institution means a preschool, a public or private elementary or secondary school, an institution of undergraduate or graduate higher education, an institution of professional education, or an institution of vocational education, which operates a program or programs of scholarly research. A requester in this fee category must show that the request is authorized by, and is made under the auspices of, an educational institution and that the records are not sought for a commercial use, but rather are sought to further scholarly research. To fall within this fee category, the request must serve the scholarly research goals of the institution rather than an individual research goal.

(1) Example 1. A request from a professor of geology at a university for records relating to soil erosion, written on letterhead of the Department of Geology, would be presumed to be from an educational institution.

(2) Example 2. A request from the same professor of geology seeking drug information from the Food and Drug Administration in furtherance of a murder mystery he is writing would not be presumed to be an institutional request, regardless of whether it was written on institutional stationery.

(3) Example 3. A student who makes a request in furtherance of the completion of a

course of instruction would be presumed to be carrying out an individual research goal, rather than a scholarly research goal of the institution and would not qualify as part of this fee category.

Fee waiver means the waiver or reduction of fees if a requester can demonstrate meeting the statutory standard that the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

FOIA means the Freedom of Information Act, 5 U.S.C. 552, as amended. The FOIA applies to requests for agency records.

FOIA Officer means the individual to whom the Council has delegated authority to carry out the Council's day-to-day FOIA administration, currently delegated to the Council's Attorney Advisor.

FOIA Public Liaison means the individual designated by the Chairperson to assist FOIA requesters with concerns about the Council's processing of their FOIA request, including assistance in resolving disputes, currently delegated to the Council's Attorney Advisor.

Non-commercial scientific institution means an organization operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any product or research, and not operated on a commercial basis.

Person includes an individual, partnership, corporation, association, or public or private organization other than an agency.

Record means any writing, drawing, map, recording, diskette, DVD, CD–ROM, tape, film, photograph, or other documentary material, regardless of medium, by which information is preserved, including documentary material stored electronically.

Redact means delete or mark over.

Representative of the news media is any person or entity organized and operated to publish or broadcast news to the public that actively gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term ''news'' means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations that broadcast ''news'' to the public at large and publishers of periodicals that disseminate ''news'' and make their products available through a variety of means to the general public, including news organizations that disseminate solely on the Internet. A request for records supporting the news-dissemination function of the requester shall not be considered to be for a commercial use. ''Freelance'' journalists who demonstrate a solid basis for expecting publication through a news media entity shall be considered as a representative of the news media. A publishing contract would provide the clearest evidence that publication is expected; however, components shall also consider a requester's past publication record in making this determination.

Requester category means one of the three categories defined by the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget (OMB Fee Guidelines) in which requesters will be placed for the purpose of determining what if any fees for search, review, or duplication may be assessed. They are:

(1) Commercial requestors;

(2) Non-commercial scientific or educational institutions or representatives of the news media; and

(3) All other requestors.

Submitter means any person or entity from whom the Council obtains confidential or privileged business information, directly or indirectly.

Unusual circumstances exist when:

(1) The need to search for and collect the requested records from physically separate facilities;

(2) The need to search for, collect and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request.

§ 10000.3 Availability of records.

Records that are required by the FOIA to be made available for public inspection and copying may be accessed through the Agency's Web site at *www.ncd.gov.* The Council is responsible for determining which of its records are required to be made publicly available, as well as identifying additional records of interest to the public that are appropriate for public disclosure, and for posting and indexing such records. The Council shall ensure that its Web site of posted records and indices is reviewed and updated on an ongoing basis. The Council's FOIA Public Liaison can assist individuals in locating records particular to a component.

§ 10000.4 Categories of exemptions.

(a) The FOIA does not require disclosure of matters that are:

(1) Specifically authorized under criteria established by an executive order to be kept secret in the interest of national defense or foreign policy and are, in fact, properly classified under executive order;

(2) Related solely to the internal personnel rules and practices of the Council;

(3) Specifically exempted from disclosure by statute (other than the Government in the Sunshine Act, 5 U.S.C. 552b, as amended), provided that such statute:

(i)(A) Requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or

(B) Establishes particular criteria for withholding or refers to particular types of matters to be withheld; and

(ii) If enacted after October 28, 2009, specifically cites to Exemption 3 of the FOIA, 5 U.S.C. 552(b)(3);

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) Inter-agency or intra-agency memoranda or letters, which would not be available at law to a party other than an agency in litigation with the Council;

(6) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information:

(i) Could reasonably be expected to interfere with enforcement proceedings;

(ii) Would deprive a person of a right to a fair trial or impartial adjudication;

(iii) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(iv) Could reasonably be expected to disclose the identity of a confidential source, including a state, local, or foreign agency or authority or any private institution that furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(v) Would disclose techniques and procedures for law enforcement investigations or prosecutions or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(vi) Could reasonably be expected to endanger the life or physical safety of any individual.

(8) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) Geological and geophysical information and data, including maps, concerning wells.

§ 10000.5 Request for records.

(a) You may request copies of records under this part by email to *FOIA@ncd.gov* or in writing addressed to FOIA Officer, National Council on Disability, 1331 F Street NW., Suite 850, Washington, DC 20004.

(b) Your request shall reasonably describe the records sought with sufficient specificity, and when possible, include names, dates, and subject matter, in order to permit the FOIA Officer to locate the records with a reasonable amount of effort. If the FOIA Officer cannot locate responsive records based on your written description, you will be notified and advised that further identifying information is necessary before the request can be fulfilled. Although requests are considered either FOIA or Privacy Act requests, the Council processes requests for records in accordance with both laws so as to provide the greatest degree of lawful access while safeguarding an individual's personal privacy.

(c) Your request should specify your preferred form or format (including electronic formats) for the records you seek. We will accommodate your request if the record is readily available in that form or format. When you do not specify the form or format of the response, we will provide responsive records in the form or format most convenient to us.

§ 10000.6 Responsibility for responding to requests.

(a) *In general.* The Council delegates authority to grant or deny FOIA requests in whole or in part to the Chief FOIA Officer. When conducting a search for responsive records, the FOIA Officer generally will search for records in existence on the date of the search. If another date is used, the FOIA Officer shall inform the requester of the date used.

(b) *Responses.* The Chief FOIA Officer will notify you of his or her determination to grant or deny your FOIA request in the time frame stated in § 10000.8. The Council will release reasonably segregable non-exempt information. For any adverse determination, including those regarding any disputed fee matter; a denial of a request for a fee waiver; or a determination to withhold a record, in whole or in part, that a record does not exist or cannot be located; or to deny a request for expedited processing; the notice shall include the following information:

(1) FOIA case number and date of the original request;

(2) The name(s) of any person responsible for the determination to deny the request in whole or in part;

(3) A brief statement of the reason(s) for the denial, including any FOIA exemption applied in denying the request. The FOIA Officer will indicate, if technically feasible, the amount of information deleted and the exemption under which a deletion is made on the released portion of the record, unless including that indication would harm an interest protected by the exemption;

(4) An estimate of the volume of information withheld, if applicable. This estimate does not need to be provided if it is ascertainable based on redactions in partially disclosed records or if the disclosure of the estimate would harm an interest protected by an applicable FOIA exemption; and

(5) A statement that the adverse determination may be appealed and a description of the requirements for an appeal under § 10000.7.

(c) *Consultation, referral, and coordination.* When reviewing records located by the Council in response to a request, the Council shall determine whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA and, if so, whether it should be released as a matter of discretion. As to any such record, the Council shall proceed in one of the following ways:

(1) *Consultation.* When records originated with the Council, but contain within them information of interest to another agency, the Council should typically consult with that other agency prior to making a release determination.

(2) *Referral.* (i) When the Council believes that a different agency is best able to determine whether to disclose the record, the Council typically should refer the responsibility for responding to the request regarding that record, as long as the referral is to an agency that is subject to the FOIA. Ordinarily, the agency that originated the record will be presumed to be best able to make the disclosure determination. However, if the Council and the originating agency jointly agree that the former is in the best position to respond regarding the record, then the record may be handled as a consultation.

(ii) Whenever the Council refers any part of the responsibility for responding to a request to another agency, it shall document the referral, maintain a copy of the record that it refers, and notify the requester of the referral and inform the requester of the name(s) of the agency to which the record was referred, including that agency's FOIA contact information.

(3) *Coordination.* The standard referral procedure is not appropriate where disclosure of the identity of the agency to which the referral would be made could harm an interest protected by an applicable exemption, such as the exemptions that protect personal privacy or national security interests. For example, if the Council responding to a request for records on a living third party locates within its files records originating with a law enforcement agency, and if the existence of that law enforcement interest in the third party was not publicly known, then to disclose that law enforcement interest could cause an unwarranted invasion of the personal privacy of the third party. Similarly, if the Council locates within its files material originating with an Intelligence Community agency, and the involvement of that agency in the matter is classified and not publicly acknowledged, then to disclose or give attribution to the involvement of that Intelligence Community agency could cause national security harms. In such instances, in order to avoid harm to an interest protected by an applicable exemption, the Council should coordinate with the originating agency to seek its views on the disclosability of the record. The release determination for the record that is the subject of the coordination should then be conveyed to the requester by the Council.

§ 10000.7 Administrative appeals.

(a) You may appeal an adverse determination related to your FOIA request, or the Council's failure to respond to your FOIA request within the prescribed time limits, to the Executive Director, National Council on Disability, 1331 F Street, NW., Suite 850, Washington, DC 20004.

(b) Your appeal must be in writing and must be postmarked or electronically received by the Executive Director within 60 days of the date of the letter denying your request, in whole or in part. For the most expeditious handling, your appeal letter and envelope should be marked ''Freedom of Information Act Appeal'' and reference the request number.

(c) The Executive Director shall respond to all administrative appeals in writing and within the time frame stated in § 10000.8(d). If the decision affirms, in whole or in part, the Chief FOIA Officer's determination, the letter shall contain a statement of the reasons for the affirmance, including any FOIA exemption(s) applied, and will inform you of the FOIA's provisions for court review. If the Executive Director reverses or modifies the Chief FOIA Officer's determination, in whole or in part, you will be notified in writing and your request will be reprocessed in accordance with that decision. The Council may work with Office of Government Information Services (OGIS) to resolve disputes between FOIA requestors and the Council. A requester may also contact OGIS in the following ways: Via mail to OGIS, National Archives and Records Administration, 8601 Adelphi Road—OGIS, College Park, MD 20740 (*ogis.archives.gov*), via email at *ogis@nara.gov,* or via the telephone at 202–741–5770 or 877–684–6448. Facsimile is also available at 202–741–5769.

§ 10000.8 Timeframe for Council's response to a FOIA request or administrative appeal.

(a) *In general.* The Council ordinarily shall respond to requests according to their order of receipt.

(b) *Multi-track processing.* (1) The Council may use two or more processing tracks by distinguishing between simple and more complex requests based on the amount of work and/or time needed to process the request, including through limits based on the number of pages involved. If the Council does so, it shall advise requesters in its slower track(s) of the limits of its faster track(s).

(2) Using multitrack processing, the Council may provide requesters in its slower track(s) with an opportunity to limit the scope of their requests in order to qualify for faster processing within the specified limits of the Council's faster track(s). In doing so, the Council will contact the requester by telephone, letter, or email, whichever is more efficient in each case.

(c) *Initial decisions.* The Council shall determine whether to comply with a FOIA request within 20 working days after our receipt of the request, unless the time frame for response is extended due to unusual circumstances as further described in paragraph (f) of this section. A request is received by the Council, for purposes of commencing the 20-day timeframe for its response, on the day it is properly received by the FOIA Officer. The request must meet all requirements described by these regulations and the FOIA before the 20-day timeframe commences.

(d) *Administrative appeals.* The Executive Director shall determine whether to affirm or overturn a decision subject to administrative appeal within 20 working days after receipt of the appeal, unless the time frame for response is extended in accordance with paragraph (e) of this section.

(e) *Tolling timelines.* We may toll the 20-day timeframe set forth in paragraph (c) or (d) of this section:

(1) One time to await information that we reasonably requested from you, as permitted by 5 U.S.C. 552(a)(6)(A)(iii)(I);

(2) As necessary to clarify with you any fee-related issue.

(3) If we toll the time frame for response under paragraphs (e)(1) or (2) of this section, the tolling period ends upon our receipt of your response.

(f) *Unusual circumstances.* In the event of unusual circumstances, we may extend the time frame for response provided in paragraph (c) or (d) of this section by providing you with written notice of the unusual circumstances and the date on which a determination is expected to be made. Where the extension is for more than ten working days, we will provide you with an opportunity either to modify your request so that it may be processed within the statutorily-prescribed time limits or to arrange an alternative time period for processing your request or modified request.

(g) *Aggregating requests.* When we reasonably believe that multiple requests submitted by a requester, or by a group of requesters acting in concert, involving clearly related matters, can be viewed as a single request that involves unusual circumstances, we may aggregate the requests for the purposes of fees and processing activities.

(h) *Expedited processing.* You may request that the Council expedite processing of your FOIA request. To receive expedited processing, you must demonstrate a compelling need for such processing.

(1) For requests for expedited processing, a ''compelling need'' involves:

(i) Circumstances in which the lack of expedited treatment could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) A request made by a person primarily engaged in disseminating information, with a time urgency to inform the public of actual or alleged federal government activity.

(2) Your request for expedited processing must be in writing and may be made at the time of the initial FOIA request or at any later time.

(3) Your request for expedited processing must include a statement, certified to be true and correct to the best of your knowledge and belief, explaining in detail the basis for requesting expedited processing. If you are a person primarily engaged in disseminating information, you must establish a particular urgency to inform the public about the federal government activity involved in the request.

(4) The FOIA Officer will decide whether to grant or deny your request for expedited processing and notify the requester within ten calendar days of receipt. You will be notified in writing of the determination. Appeals of adverse decisions regarding expedited processing shall be processed expeditiously.

§ 10000.9 Business information.

(a) *Designation of confidential business information.* In the event a FOIA request is made for confidential business information previously submitted to the Government by a commercial entity or on behalf of it (hereinafter ''submitter''), the regulations in this section apply. When submitting confidential business information, you must use a good-faith effort to designate, by use of appropriate markings, at the time of submission or at a reasonable time thereafter, any portions of your submission that you consider to be exempt from disclosure under FOIA Exemption 4, 5 U.S.C. 552(b)(4). Your designation will expire ten years after the date of submission unless you request, and provide justification for, a longer designation period.

(b) *Notice to submitters.* (1) Whenever you designate confidential business information as provided in paragraph (a) of this section, or the Council has reason to believe that your submission may contain confidential business information, we will provide you with prompt written notice of a FOIA request that seeks your business information. The notice shall:

(i) Give you an opportunity to object to disclosure of your information, in whole or in part;

(ii) Describe the business information requested or include copies of the requested records or record portions containing the information; and

(iii) Inform you of the time frame in which you must respond to the notice.

(2) In cases involving a voluminous number of submitters, notice may be made by posting or publishing the notice in a place or manner reasonably likely to accomplish it.

(c) *Opportunity to object to disclosure.* The Council shall allow you a reasonable time to respond to the notice described in paragraph (b) of this section. If you object to the disclosure of your information, in whole or in part, you must provide us with a detailed written statement of your objection. The statement must specify all grounds for withholding any portion of the information under any FOIA exemption and, when relying on FOIA Exemption 4, it must explain why the information is a trade secret or commercial or financial information that is privileged and confidential. If you fail to respond within the time frame specified in the notice, the Council will conclude that you have no objection to disclosure of your information. The Council will only consider information that we receive within the time frame specified in the notice.

(d) *Notice of intent to disclose.* The Council will consider your objection and specific grounds for non-disclosure in deciding whether to disclose business information. Whenever the Council decides to disclose business information over your objection, we will provide you with written notice that includes:

(1) A statement of the reasons why each of your bases for withholding were not sustained;

(2) A description of the business information to be disclosed; and

(3) A specified disclosure date, which shall be a reasonable time after the notice.

(e) *Exceptions to the notice requirement.* The notice requirements of paragraphs (c) and

(d) of this section shall not apply if:

(1) The Council determines that the information is exempt under the FOIA;

(2) The information lawfully has been published or has been officially made available to the public;

(3) Disclosure of the information is required by statute (other than the FOIA) or by a regulation issued in accordance with the requirements of Executive Order 12600;

(4) The designation made by the submitter under paragraph (a) of this section appears obviously frivolous, except that, in such a case, the Council shall, within a reasonable time prior to the date the disclosure will be made, give the submitter written notice of the final decision to disclose the information.

(f) *Requester notification.* The Council shall notify a requester whenever it provides the submitter with notice and an opportunity to object to disclosure; whenever it notifies the submitter of its intent to disclose the requested information; and whenever a submitter files a lawsuit to prevent the disclosure of the information.

§ 10000.10 Fees.

(a) We will charge fees that recoup the full allowable direct costs we incur in processing your FOIA request. Fees may be charged for search, review or duplication. We will use the most efficient and least costly methods to comply with your request.

(b) With regard to manual searches for records, we will charge the salary rate(s) (calculated as the basic rate of pay plus 16 percent of that basic rate to cover benefits) of the employee(s) performing the search.

(c) In calculating charges for computer searches for records, we will charge at the actual direct cost of providing the service, including the cost of operating the central processing unit directly attributable to searching for records potentially responsive to your FOIA request and the portion of the salary of the operators/programmers performing the search.

(d) Review fees shall be charged for requesters who make commercial use requests. Review fees shall be assessed only for the initial review—that is the review undertaken the first time we analyze the applicability of a specific exemption to a particular record or portion of a record. Records or portions of records withheld in full under an exemption that is subsequently determined not to apply may be reviewed again to determine the applicability of other exemptions not previously considered. We may assess the costs for such subsequent review. Review fees are charged at the same rates as those charged for a search.

(e) Notice of anticipated fees in excess of $25.00:

(1) When the Council determines or estimates that the fees to be assessed in accordance with this section will exceed $25.00, the Council shall notify the requester of the actual or estimated amount of the fees, including a breakdown of the fees for search, review or duplication, unless the requester has indicated a willingness to pay fees as high as those anticipated. If only a portion of the fee can be estimated readily, the Council shall advise the requester accordingly. If the requester is a noncommercial use requester, the notice shall specify that the requester is entitled to the statutory entitlements of 100 pages of duplication or equivalent at no charge. For example, 100 pages burned to a single CD would be considered equivalent to 100 pages of duplication. And, if the requester is charged search fees, two hours of search time at no charge, and shall advise the requester whether those entitlements have been provided.

(2) In cases in which a requester has been notified that the actual or estimated fees are in excess of $25.00, the request shall not be considered received and further work will not be completed until the requester commits in writing to pay the actual or estimated total fee, or designates some amount of fees the requester is willing to pay, or in the case of a noncommercial use requester who has not yet been provided with the requester's statutory entitlements, designates that the requester seeks only that which can be provided by the statutory entitlements. The requester must provide the commitment or designation in writing, and must, when applicable, designate an exact dollar amount the requester is willing to pay. The Council is not required to accept payments in installments.

(3) If the requester has indicated a willingness to pay some designated amount of fees, but the Council estimates that the total fee will exceed that amount, the Council shall toll the processing of the request when it notifies the requester of the estimated fees in excess of the amount the requester has indicated a willingness to pay. The Council shall inquire whether the requester wishes to revise the amount of fees the requester is willing to pay or modify the request. Once the requester responds, the time to respond will resume from where it was at the date of the notification.

(4) The Council shall make available its FOIA Public Liaison or other FOIA professional to assist any requester in reformulating a request to meet the requester's needs at a lower cost.

(f) We will charge you the full costs of providing you with the following services:

(1) Certifying that records are true copies; or

(2) Sending records by special methods such as express or certified mail.

(g) We may assess interest charges on an unpaid bill starting on the 31st calendar day following the day on which the billing was sent. Interest shall be at the rate prescribed in 31 U.S.C. 3717 and will accrue from the date of the billing.

(h) We will not charge a search fee for requests by educational institutions, non-commercial scientific institutions, or representatives of the news media. A search fee will be charged for a commercial use requests.

(i) Except for a commercial use request, we will not charge you for the

first 100 pages of duplication and the first two hours of search.

(j) If the Council fails to comply with the time limits in which to respond to a request, and if no unusual or exceptional circumstances, as those terms are defined by the FOIA, apply to the processing of the request, it may not charge search fees, or, in the instances of requests from requesters requests by educational institutions (unless the records are sought for a commercial use), noncommercial scientific institutions, or representatives of the news media, may not charge duplication fees.

(k) After processing, actual fees must be equal to or exceed $25, for the Council to require payment of fees.

(l) You may not file multiple requests, each seeking portions of a document or documents, solely for the purpose of avoiding payment of fees. When the Council reasonably believes that a requester, or a group of requesters acting in concert, has submitted requests that constitute a single request involving clearly related matters, we may aggregate those requests and charge accordingly.

(m) We may not require you to make payment before we begin work to satisfy the request or to continue work on a request, unless:

(1) We estimate or determine that the allowable charges that you may be required to pay are likely to exceed $250; or

(2) You have previously failed to pay a fee charged within 30 days of the date of billing.

(n) Upon written request, we may waive or reduce fees that are otherwise chargeable under this part. If you request a waiver or reduction in fees, you must demonstrate that a waiver or reduction in fees is in the public interest because disclosure of the requested records is likely to contribute significantly to the public understanding of the operations or activities of the government and is not primarily in your commercial interest.

(1) In deciding whether disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government, the Council shall consider all four of the following factors:

(i) The subject of the request must concern identifiable operations or activities of the Federal Government, with a connection that is direct and clear, not remote or attenuated.

(ii) Disclosure of the requested records must be meaningfully informative about government operations or activities in order to be ''likely to contribute'' to an increased public understanding of those operations or activities. The disclosure of information that already is in the public domain, in either the same or a substantially identical form, would not contribute to such understanding where nothing new would be added to the public's understanding.

(iii) The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area as well as the requester's ability and intention to effectively convey information to the public shall be considered. It shall be presumed that a representative of the news media will satisfy this consideration.

(iv) The public's understanding of the subject in question must be enhanced by the disclosure to a significant extent. However, components shall not make value judgments about whether the information at issue is ''important'' enough to be made public.

(2) To determine whether disclosure of the requested information is primarily in the commercial interest of the requester, the Council shall consider the following factors:

(i) The Council shall identify any commercial interest of the requester, as defined in § 10000.2, that would be furthered by the requested disclosure. Requesters shall be given an opportunity to provide explanatory information regarding this consideration.

(ii) A waiver or reduction of fees is justified where the public interest is greater than any identified commercial interest in disclosure. The Council ordinarily shall presume that where a news media requester has satisfied the public interest standard, the public interest will be the interest primarily served by disclosure to that requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return shall not be presumed to primarily serve the public interest.

(3) Where only some of the records to be released satisfy the requirements for a waiver of fees, a waiver shall be granted for those records.

(4) Requests for a waiver or reduction of fees should be made when the request is first submitted to the component and should address the criteria referenced above. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester shall be required to pay any costs incurred up to the date the fee waiver request was received.

PART 10001—IMPLEMENTATION OF THE PRIVACY ACT OF 1974

Sec.

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

§ 10001.1 Purpose and scope.

The regulations in this part implement the provisions of the Privacy Act.

§ 10001.2 Definitions.

The following terms used in this part are defined in the Privacy Act: *Individual, maintain, record, routine use, statistical record, system of records.* The following definitions also apply in this part:

Chairperson means the Chairperson of the Council, as appointed by the President, or any person to whom the Council has delegated authority for the matter concerned.

Council means the National Council on Disability, established by the Rehabilitation Act of 1973 (29 U.S.C. 780 *et seq.*), as amended, and amended by the Workforce Innovation and Opportunity Act (Pub. L. 113–128) in 2014.

General Counsel means the Council's principal legal advisor, or his or her designee.

Privacy Act means the Privacy Act of 1974, 5 U.S.C. 552a, as amended.

Privacy Act Officer means the person designated by the Council to be responsible for the day-to-day administration of the Privacy Act, currently delegated to the Council's Management Analyst.

§ 10001.3 Privacy Act requests.

(a) *Requests to determine if you are the subject of a record.* You may request that the Council inform you if we maintain a system of records that contains records about you. Your request must follow the procedures described in paragraph (b) of this section.

(b) *Requests for access.* You may request access to a Council record about you in writing or by appearing in person. You should direct your request to the Privacy Act Officer. Written requests may be sent to: Privacy Act

Officer, National Council on Disability, 1331 F Street NW., Suite 850, Washington, DC 20004. Your request should include the following information:

(1) Your name, address, and telephone number;

(2) The system(s) of records in which the requested information is contained; and

(3) At your option, authorization for copying expenses.

(4) *Written requests.* In addition to the information described in paragraphs (b)(1) through (3) of this section, written requests must include a statement affirming your identity, signed by you and witnessed by two persons (including witnesses' addresses) or notarized.

(i) *Witnessed.* If your statement is witnessed, it must include a sentence above the witnesses' signatures attesting that they personally know you or that you have provided satisfactory proof of your identity.

(ii) *Notarized.* If your statement is notarized, you must provide the notary with adequate proof of your identity in the form of a drivers' license, passport, or other identification acceptable to the notary.

(iii) The Council, in its discretion, may require additional proof of identification depending on the nature and sensitivity of the records in the system of records(iv) For the quickest possible handling, your letter and envelope should be marked ''Privacy Act Request.''

(5) *In person requests.* In addition to the information described in paragraphs (b)(1) through (3) of this section, if you make your request in person, you must provide adequate proof of identification at the time of your request. Adequate proof of identification includes a valid drivers' license, valid passport, or other current identification that includes your address and photograph.

(c) *Requests for amendment or correction of records.* You may request an amendment to or correction of a record about you in person or by writing to the Privacy Act Officer following the procedures described in paragraph (b) of this section. Your request for amendment or correction should identify each particular record at issue, state the amendment or correction sought, and describe why the record is not accurate, relevant, timely, or complete.

(d) *Requests for an accounting of disclosures.* Except for those disclosures for which the Privacy Act does not require an accounting, you may request an accounting of any disclosure by the Council of a record about you. Your request for an accounting of disclosures must be made in writing following the procedures described in paragraph (b) of this section.

(e) *Requests for access on behalf of someone else.* (1) If you are making a request on behalf of someone else, your request must include a statement from that individual verifying his or her identity, as provided in paragraph (b)(4) of this section. Your request also must include a statement certifying that individual's agreement that records about him or her may be released to you.

(2) If you are the parent or guardian of the individual to whom the requested record pertains, or the individual to whom the record pertains has been deemed incompetent by a court, your request for access to records about that individual must include:

(i) The identity of the individual who is the subject of the record, including his or her name, current address, and date and place of birth;

(ii) Verification of your identity in accordance with paragraph (b)(4) of this section;

(iii) Verification that you are the subject's parent or guardian, which may be established by a copy of the subject's birth certificate identifying you as his or her parent, or a court order establishing you as guardian; and

(iv) A statement certifying that you are making the request on the subject's behalf.

§ 10001.4 Responses to Privacy Act requests.

(a) *Acknowledgement.* The Privacy Act Officer shall provide you with a written acknowledgment of your written request under section 3 within ten business days of our receipt of your request.

(b) *Grants of requests.* If you make your request in person, the Privacy Act Officer shall respond to your request directly, either by granting you access to the requested records, upon payment of any applicable fee and with a written record of the grant of your request and receipt of the records, or by informing you when a response may be expected. If you are accompanied by another person, you must authorize in writing any discussion of the records in the presence of the third person. If your request is in writing, the Privacy Act Officer shall provide you with written notice of the Council's decision to grant your request and the amount of any applicable fee. The Privacy Act Officer shall disclose the records to you promptly, upon payment of any applicable fee.

(c) *Denials of requests in whole or in part.* The Privacy Act Officer shall notify you in writing of his or her determination to deny, in whole or in part, your request. This writing shall include the following information:

(1) The name and title or position of the person responsible for the denial;

(2) A brief statement of the reason for the denial(s), including any applicable Privacy Act exemption;

(3) A statement that you may appeal the denial and a brief description of the requirements for appeal under § 10001.5.

(d) *Request for records not covered by the Privacy Act or subject to Privacy Act exemption.* If the Privacy Act Officer determines that a requested record is not subject to the Privacy Act or the records are subject to Privacy Act exemption, your request will be processed in accordance with the Council's Freedom of Information Act procedures at 5 CFR part 10000.

§ 10001.5 Administrative appeals.

(a) *Appeal procedures.* (1) You may appeal any decision by the Council to deny, in whole or in part, your request under § 10001.3 no later than 60 days after the decision is rendered.

(2) Your appeal must be in writing, sent to the General Counsel at the address specified in § 10001.3(b) and contain the following information:

(i) Your name;

(ii) Description of the record(s) at issue;

(iii) The system of records in which the record(s) is contained;

(iv) A statement of why your request should be granted.

(3) The General Counsel shall determine whether to uphold or reverse the initial determination within 30 working days of our receipt of your appeal. The General Counsel shall notify you of his or her decision, including a brief statement of the reasons for the decision, in writing. The General Counsel's decision will be the final action of the Council.

(b) *Statement of disagreement.* If your appeal of our determination related to your request for amendment or correction is denied in whole or in part, you may file a Statement of Disagreement that states the basis for your disagreement with the denial. Statements of Disagreement must be concise and must clearly identify each part of any record that is disputed. The Privacy Act Officer will place your Statement of Disagreement in the system of records in which the disputed record is maintained and shall mark the disputed record to indicate that a

Statement of Disagreement has been filed and where it may be found.

(c) *Notification of amendment, correction, or disagreement.* Within 30 working days of the amendment or correction of a record, the Privacy Act Officer shall notify all persons, organizations, or agencies to which the Council previously disclosed the record, if an accounting of that disclosure was made, that the record has been corrected or amended. If you filed a Statement of Disagreement, the Privacy Act Officer shall append a copy of it to the disputed record whenever it is disclosed and also may append a concise statement of its reason(s) for denying the request to amend or correct the record.

§ 10001.6 Fees.

We will not charge a fee for search or review of records requested under this part, or for the correction of records. If you request copies of records, we may charge a fee of $.10 per page.

§ 10001.7 Penalties.

Any person who makes a false statement in connection with any request for a record or an amendment or correction thereto under this part is subject to the penalties prescribed in 18 U.S.C. 494 and 495 and 5 U.S.C. 552a(i)(3).

PART 10002—IMPLEMENTATION OF THE GOVERNMENT IN THE SUNSHINE ACT

Sec.

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

§ 10002.1 Purpose and scope.

(a) The regulations in this part implement the provisions of the Sunshine Act.

(b) Requests for all records other than those described in § 10002.9, shall be governed by the Council's Freedom of Information Act procedures at 5 CFR part 10001.

§ 10002.2 Definitions.

The following definitions apply in this part:

Chairperson means the Chairperson of the Council, as appointed by the President, or any person to whom the Council has delegated authority for the matter concerned.

Council means the National Council on Disability, established by the Rehabilitation Act of 1973 (29 U.S.C. 780 *et seq.*), as amended, and amended by the Workforce Innovation and Opportunity Act (Pub. L. 113–128) in 2014.

General Counsel means the Council's principal legal advisor, or his or her designee.

Meeting means the deliberations of five or more Council members that determine or result in the joint conduct or disposition of official Council business. A meeting does not include:

(1) Notational voting or similar consideration of business for the purpose of recording votes, whether by circulation of material to members' individually in writing or by a polling of the members individually by phone or email.

(2) Action by five or more members to:

(i) Open or close a meeting or to release or withhold information pursuant to § 10002.6;

(ii) Set an agenda for a proposed meeting;

(iii) Call a meeting on less than seven days' notice, as permitted by § 10002.4; or

(iv) Change the subject matter or the determination to open or to close a publicly announced meeting under § 10002.7.

(3) A session attended by five or more members for the purpose of having the Council's staff or expert consultants, another federal agency, or other persons or organizations brief or otherwise provide information to the Council concerning any matters within the purview of the Council, provided that the members do not engage in deliberations that determine or result in the joint conduct or disposition of official business on such matters.

(4) A gathering of members for the purpose of holding informal, preliminary discussions or exchanges of views which do not effectively predetermine official action.

Member means an individual duly appointed and confirmed to the Council.

Public observation means attendance by the public at a meeting of the Council, but does not include public participation.

Public participation means the presentation or discussion of information, raising of questions, or other manner of involvement in a meeting of the Council by the public in a manner that contributes to the disposition of official Council business.

Sunshine Act means the Government in the Sunshine Act, 5 U.S.C. 552b.

§ 10002.3 Open meetings.

(a) Except as otherwise provided in this part, every portion of a Council meeting shall be open to public observation.

(b) Council meetings, or portions thereof, shall be open to public participation when an announcement to that effect is published under § 10002.4. Public participation shall be conducted in an orderly, non-disruptive manner and in accordance with any procedures the Chairperson may establish. Public participation may be terminated for good cause as determined by the Council upon the advice of the General Counsel based on unanticipated developments.

§ 10002.4 Procedures for public announcement of meetings.

(a) Except as otherwise provided in this section, the Council shall make a public announcement at least seven days prior to a meeting. The public announcement shall include:

(1) The time and place of the meeting;

(2) The subject matter of the meeting;

(3) Whether the meeting is to be open, closed, or portions of a meeting will be closed;

(4) Whether public participation will be allowed;

(5) The name and telephone number of the person who will respond to requests for information about the meeting;

(b) The seven-day prior notice required by paragraph (a) of this section may be reduced only if:

(1) A majority of all members determine by recorded vote that Council business requires that such meeting be scheduled in less than seven days; and

(2) The public announcement required by this section is made at the earliest practicable time.

(c) If public notice is provided by means other than publication in the **Federal Register**, notice will be promptly submitted to the **Federal Register** for publication.

§ 10002.5 Grounds on which meetings may be closed or information withheld.

A meeting, or portion thereof, may be closed and information pertinent to such meeting withheld if the Council determines that the meeting or release of information is likely to disclose matters that are:

(a) Specifically authorized under criteria established by an executive

order to be kept secret in the interests of national defense or foreign policy; and, in fact, are properly classified pursuant to such executive order. In making the determination that this exemption applies, the Council shall rely on the classification assigned to the document or assigned to the information from the federal agency from which the document was received.

(b) Related solely to the internal personnel rules and practices of the Council;

(c) Specifically exempt from disclosure by statute (other than 5 U.S.C. 552), provided that such statute:

(1) Requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or

(2) Establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(d) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(e) Involved with accusing any person of a crime or formally censuring any person;

(f) Of a personal nature, if disclosure would constitute a clearly unwarranted invasion of personal privacy;

(g) Either investigatory records compiled for law enforcement purposes or information which, if written, would be contained in such records, but only to the extent that the production of records or information would:

(1) Interfere with enforcement proceedings;

(2) Deprive a person of a right to either a fair trial or an impartial adjudication;

(3) Constitute an unwarranted invasion of personal privacy;

(4) Disclose the identity of a confidential source or sources and, in the case of a record compiled either by a criminal law enforcement authority or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source(s);

(5) Disclose investigative techniques and procedures; or

(6) Endanger the life or physical safety of law enforcement personnel;

(h) Contained in or relating to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions;

(i) If prematurely disclosed, likely to significantly frustrate implementation of a proposed action of the Council, except that this subsection shall not apply in any instance where the Council has already disclosed to the public the content or nature of its proposed action or is required by law to make such disclosure on its own initiative prior to taking final action on such proposal; and

(j) Specifically concerned with the Council's issuance of a subpoena, or its participation in a civil action or proceeding, an action in a foreign court or international tribunal, or an arbitration, or the initiation, conduct, or disposition by the Council of a particular case or formal agency adjudication pursuant to the procedures in 5 U.S.C. 554 or otherwise involving a determination on the record after opportunity for a hearing.

§ 10002.6 Procedures for closing meetings or withholding information, and requests by affected persons to close a meeting.

(a) A meeting or portion of a meeting may be closed and information pertaining to a meeting withheld under § 10002.5 only by vote of a majority of members.

(b) A separate vote of the members shall be taken with respect to each meeting or portion of a meeting proposed to be closed and with respect to information which is proposed to be withheld. A single vote may be taken with respect to a series of meetings or portions of a meeting that are proposed to be closed, so long as each meeting or portion thereof in the series involves the same particular matter and is scheduled to be held no more than 30 days after the initial meeting in the series. The vote of each member shall be recorded and no proxies shall be allowed.

(c) A person whose interests may be directly affected by a portion of a meeting may request in writing that the Council close that portion for any of the reasons referred to in § 10002.5(e) through (g). Upon the request of a member, a recorded vote shall be taken whether to close such meeting or portion thereof.

(d) For every meeting closed, the General Counsel shall publicly certify that, in his or her opinion, the meeting may be closed to the public and shall state each relevant basis for closing the meeting. If the General Counsel invokes the bases set forth in § 10002.5(a) or (c), he or she shall rely upon the classification or designation assigned to the information by the originating agency. A copy of such certification, together with a statement by the presiding officer setting forth the time and place of the meeting and the persons present, shall be retained by the Council as part of the transcript, recording, or minutes required by § 10002.8.

§ 10002.7 Changes following public announcement.

(a) The time or place of a meeting may be changed following the public announcement described in § 10002.4. The Council must publicly announce such change at the earliest practicable time.

(b) The subject matter of a meeting or the determination of the Council to open or close a meeting, or a portion thereof, to the public may be changed following public announcement only if:

(1) A majority of all members determine by recorded vote that Council business so requires and that no earlier announcement of the change was possible; and

(2) The Council publicly announces such change and the vote of each member thereon at the earliest practicable time.

§ 10002.8 Transcripts, recordings, or minutes of closed meetings.

Along with the General Counsel's certification and presiding officer's statement referred to in § 10002.6(d), the Council shall maintain a complete transcript or electronic recording adequate to record fully the proceedings of each meeting, or a portion thereof, closed to the public. Alternatively, for any meeting closed pursuant to § 10002.5(h) or (j), the Council may maintain a set of minutes adequate to record fully the proceedings, including a description of each of the views expressed on any item and the record of any roll call vote.

§ 10002.9 Public availability and retention of transcripts, recordings, and minutes, and applicable fees.

(a) The Council shall make available, in a place easily accessible, such as *www.ncd.gov,* to the public the transcript, electronic recording, or minutes of a meeting, except for items of discussion or testimony related to matters the Council determines may be withheld under § 10002.6.

(b) Copies of the nonexempt portions of the transcripts or minutes shall be provided upon receipt of the actual costs of the transcription or duplication.

(c) The Council shall maintain meeting transcripts, recordings, or minutes of each meeting closed to the public for a period ending at the later of two years following the date of the meeting, or one year after the conclusion of any Council proceeding with respect to the closed meeting.

PARTS 10003–10049—[RESERVED]

Dated: August 11, 2015.

Rebecca Cokley,

Executive Director.

[FR Doc. 2015–20140 Filed 8–14–15; 8:45 am]

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BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1010

Compliance Bulletin—Amendment to the Interstate Land Sales Full Disclosure Act

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Compliance bulletin.

SUMMARY: The Bureau of Consumer Financial Protection is issuing a compliance bulletin titled ''Amendment to the Interstate Land Sales Full Disclosure Act'' to provide information to developers and other interested parties relating to a recent Congressional amendment to the Interstate Land Sales Full Disclosure Act.

DATES: This bulletin is applicable August 17, 2015.

FOR FURTHER INFORMATION CONTACT: Amanda Quester, Senior Counsel, Office of Regulations, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Compliance Bulletin

The Consumer Financial Protection Bureau (Bureau) issues this compliance bulletin to provide information to developers and other interested parties relating to Public Law 113–167, 128 Stat. 1882 (2014), which amended the Interstate Land Sales Full Disclosure Act (ILSA). This ILSA amendment was signed by the President on September 26, 2014. It became effective on March 25, 2015, and is codified primarily at 15 U.S.C. 1702(b)(9) and (d).

The amendment exempts from ILSA's registration and disclosure requirements the sale or lease of a condominium unit that is not exempt under 15 U.S.C. 1702(a). Under 15 U.S.C. 1702(d), a ''condominium unit'' is defined for purposes of this new exemption as a unit of residential or commercial property to be designated for separate ownership pursuant to a condominium plan or declaration provided that upon conveyance: (1) The owner of such unit will have sole ownership of the unit and an undivided interest in the common elements appurtenant to the unit; and (2) the unit will be an improved lot.

Pursuant to § 1010.4(d) of the Bureau's ILSA regulations, eligibility for an exemption under 15 U.S.C. 1702, including the exemption of section 1702(b)(9), is self-determining, and a developer is not required to file notice with or obtain the approval of the Bureau in order to take advantage of an exemption. Section 1010.4(d) also provides that a developer is responsible for maintaining records to demonstrate that the requirements of an exemption have been met if a developer elects to take advantage of an exemption. The Bureau will continue to process filings made by developers seeking to fulfill their obligations under ILSA and its implementing regulations.

If you have questions about ILSA program operations, you may contact ILSA program staff via email to *CFPB_ILS_Inquiries@cfpb.gov* or at the address below: Consumer Financial Protection Bureau, Interstate Land Sales Program, 1700 G St. NW., Attn: 1625 Eye St., Room 3093, Washington, DC 20552.

If you have a question regarding the interpretation of ILSA or the Bureau's implementing regulations, please email *CFPB_reginquiries@cfpb.gov* with your specific question, including reference to the applicable regulation section(s).

Bureau staff responding to queries cannot provide legal advice and are not authorized to provide official interpretations of ILSA or of the Bureau's implementing regulations.

II. Regulatory Requirements

This Compliance Bulletin summarizes existing requirements under the law, and does not itself establish any binding obligations. It is therefore exempt from notice and comment rulemaking requirements under the Administrative Procedure Act pursuant to 5 U.S.C. 553(b). Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis. 5 U.S.C. 603(a), 604(a). The Bureau has determined that this Compliance Bulletin does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

Dated: August 10, 2015.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2015–19998 Filed 8–14–15; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3398; Directorate Identifier 2015–CE–031–AD; Amendment 39–18232; AD 2015–16–07]

RIN 2120–AA64

Airworthiness Directives; REIMS AVIATION S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for REIMS AVIATION S.A. Model F406 airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as detachment of the pilot's rudder control pedal in flight. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective August 18, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of August 18, 2015.

We must receive comments on this AD by October 1, 2015.

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 AD, contact ASI Aviation, Aérodrome de Reims Prunay, 51360 Prunay, FRANCE; phone: +33 3 26 48 46 65; fax: +33 3 26 49 18 57; email: none; Internet: *http://asi-aviation.fr/asi-aviation-support/1.html* (requires user name and password). You may view this referenced service information at the FAA, Small Airplane Directorate, 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 locating Docket No. FAA–2015–3398.

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–2015–3398; 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 in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Albert J. Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4119; fax: (816) 329–4090; email: *albert.mercado@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No.: 2015–0159–E, dated July 31, 2015 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> An occurrence was reported where one pilot rudder control pedal of an F 406 aeroplane detached in flight. No change in aeroplane attitude occurred. The rudder was controlled using the co-pilot rudder pedals, and the flight continued uneventfully until a safe landing was performed.
>
> This condition, if not detected and corrected, could result in loss of directional control of the aeroplane.
>
> To address this unsafe condition, ASI Aviation issued Service Bulletin (SB) F406–104 to provide inspection instructions.
>
> For the reason described above, this AD requires inspection of the rudder control pedal torque tubes, both left-hand (LH) and right-hand (RH), and, depending on findings, replacement with a serviceable part.
>
> This AD also requires inspection before new installation of rudder control pedal torque tubes.

You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3398.

Related Service Information Under 1 CFR Part 51

ASI AVIATION has issued Service Bulletin No.: F406–104, dated July 28, 2015. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI. The service information describes procedures for inspection of the left-hand and right-hand rudder control pedal torque tubes, and, depending on findings, replacement with a serviceable part. 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 of this AD.

FAA's Determination and Requirements of the 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 issuing this AD because we evaluated all information provided by the State of Design Authority and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because detachment of the pilot rudder control pedal in flight could result in loss of airplane directional control. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–3398; Directorate Identifier 2015–CE–031–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this 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 AD.

Costs of Compliance

We estimate that this AD will affect 7 products of U.S. registry. We also estimate that it will take about 5 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of the AD on U.S. operators to be $2,975, or $425 per product.

In addition, we estimate that any necessary follow-on actions would take about 20 work-hours and require parts costing $10,000, for a cost of $11,700 per product. We have no way of determining the number of products that may need these actions.

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.

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 AD:

2015–16–07 REIMS AVIATION S.A.: Amendment 39–18232; Docket No. FAA–2015–3398; Directorate Identifier 2015–CE–031–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective August 18, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Reims Aviation S.A. Model F406 airplanes, serial numbers 0001 through 0098, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as detachment of the pilot's rudder control pedal in flight. We are issuing this AD to detect and correct cracking of the pilot rudder control pedal which, if not corrected, could result in detachment of the pedal with possible loss of airplane directional control.

(f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (f)(4) of this AD.

(1) Before further flight after August 18, 2015 (the effective date of this AD), do a visual inspection and a dye or fluorescent penetrant inspection of the rudder control pedal torque tubes, LH (Part Number (P/N) 5115260–1) and RH (P/N 5115260–2), following the instructions of PART A of ASI AVIATION Service Bulletin No.: F406–104, dated July 28, 2015.

(2) If no crack is detected during the inspection required by paragraph (f)(1) of this AD, within 100 hours time-in-service (TIS) after August 18, 2015 (the effective date of this AD), do a magnetic particle inspection of the rudder control pedal torque tubes, LH (P/N 5115260–1) and RH (P/N 5115260–2), following the instructions of PART B of ASI AVIATION Service Bulletin No.: F406–104, dated July 28, 2015.

(3) If any crack is detected on a rudder control pedal torque tube during the inspection required by paragraph (f)(1) or (f)(2) of this AD, before further flight, replace the affected part with a serviceable part following the instructions of ASI AVIATION Service Bulletin No.: F406–104, dated July 28, 2015.

(4) For the purpose of this AD, a serviceable part is a rudder control pedal torque tube that has had a magnetic particle inspection following the instructions of PART B of ASI AVIATION Service Bulletin No.: F406–104, dated July 28, 2015, and no cracks were found.

(5) You may install a rudder control pedal torque tube P/N 5115260–1 (LH) or P/N 5115260–2 (RH) on an airplane, provided it is a serviceable part.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, 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: Albert J. Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4119; fax: (816) 329–4090; email: *albert.mercado@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) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(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 European Aviation Safety Agency (EASA) AD No.: 2015–0159–E, dated July 31, 2015, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3398.

(i) 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) ASI AVIATION Service Bulletin No.: F406–104, dated July 28, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact ASI Aviation, Aérodrome de Reims Prunay, 51360 Prunay, FRANCE; phone: +33 3 26 48 46 65; fax: +33 3 26 49 18 57; email: none; Internet: *http://asi-aviation.fr/asi-aviation-support/1.html* (requires user name and password).

(4) You may view this service information at the FAA, Small Airplane Directorate, 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 locating Docket No. FAA–2015–3398.

(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 August 6, 2015.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–19901 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–1744; Directorate Identifier 2015–CE–016–AD; Amendment 39–18231; AD 2015–16–06]

RIN 2120–AA64

Airworthiness Directives; British Aerospace Regional Aircraft Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for British Aerospace Regional Aircraft Model Jetstream Model 3201 airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as the in-service special detailed inspection technique required for the Jetstream 3200's life extension program was delayed; consequently, the in-service special detailed inspection technique is not formally part of the life extension program and may therefore not be accomplished as intended. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective September 21, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of September 21, 2015.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–1744; or in person at Document 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 service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone: +44 1292 675207; fax: +44 1292 675704; email: *RApublications@baesystems.com;* Internet: *http://www.baesystems.com/Businesses/RegionalAircraft/*. You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. You may view this referenced service information at the FAA, Small Airplane Directorate, 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 Docket No. FAA–2015–1744.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to adding an AD that would apply to British Aerospace Regional Aircraft Model Jetstream Model 3201 airplanes. The NPRM was published in the **Federal Register** on May 26, 2015 (80 FR 29988). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. The MCAI states:

> The Jetstream 3200 Life Extension Programme (LEP) permits the airframe life limit to be extended from 45 000 flight cycles (FC) to 67 000 FC. Entry into the LEP requires operators to accomplish inspections specified in the Jetstream 3200 Supplemental Structural Inspections Document (SSID). SSID task 57–10–227 is the inspection requirement for the wing main spar at Rib 36. The threshold for task 57–10–227 is 48 000 FC, with a repeat interval of 16 800 FC, using a Special Detailed Inspection (SDI). Development of the in-service SDI technique required for SSID task 57–10–227 was delayed by BAE Systems (Operations) Ltd, as a result of which it is not formally part of the LEP and may therefore not be accomplished as intended.
>
> This condition, if not corrected, could lead to cracks in the wing main spar remaining undetected, possibly resulting in failure of the wing and loss of the aeroplane.
>
> To address this potential unsafe condition, BAE Systems (Operations) Ltd issued SB 57–JA140140 to provide SDI instructions for the wing main spar at Rib 36, which includes a reduced repeat inspection interval.
>
> For the reasons described above, this AD requires repetitive inspections of the wing main spar around Rib 36 to detect cracks and, depending on findings, accomplishment of the applicable corrective action(s).

The SSID will be revised in due course to include the SDI. The MCAI can be found in the AD docket on the Internet at: *http://www.regulations.gov/#!documentDetail;D=FAA-2015-1744-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (80 FR 29988, May 26, 2015) 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 the 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 (80 FR 29988, May 26, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 29988, May 26, 2015).

Related Service Information Under 1 CFR Part 51

We reviewed British Aerospace Regional Aircraft British Aerospace Jetstream Series 3100 & 3200 Service Bulletin 57–JA140140, Original Issue, dated: June 26, 2014. The service information describes procedures for inspections of the wing main spar around Rib 36 to detect cracks and, depending on findings, accomplishment of the applicable corrective action(s). 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 of this AD.

Costs of Compliance

We estimate that this AD will affect 22 products of U.S. registry. We also estimate that it will take about 96 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of the AD on U.S. operators to be $179,520, or $8,160 per product.

We have no way of determining any necessary follow-on actions, costs, or the number of products that may need these actions.

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.

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, 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.

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–2015–1744; 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 the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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 AD:

2015–16–06 British Aerospace Regional Aircraft: Amendment 39–18231; Docket No. FAA–2015–1744; Directorate Identifier 2015–CE–016–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective September 21, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to British Aerospace Regional Aircraft Jetstream Model 3201 airplanes, all serial numbers, that are:

(1) Certificated in any category; and

(2) Modified in service following BAE Systems (Operations) Ltd Service Bulletin (SB) 05- JM8229.

(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 correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as the in-service special detailed inspection technique required for the Jetstream 3200's life extension program was delayed; consequently, the in-service special detailed inspection (SDI) technique is not formally part of the life extension program and may therefore not be accomplished as intended. We are issuing this AD to detect and correct cracking in the wing main spar, which could result in structural failure of the wing with consequent loss of control.

(f) Actions and Compliance

Unless already done, do the following actions as specified in paragraphs (f)(1) through (f)(3) of this AD:

(1) Before accumulating a total of 53,950 flight cycles (FC) on the airplane or within the next 50 FC after September 21, 2015 (the effective date of this AD), whichever occurs later, and repetitively thereafter at intervals not to exceed 14,300 FC, accomplish an eddy current (EC) and an x-ray inspection of the wing main spar around rib 36 following the instructions of British Aerospace Jetstream Series 3100 & 3200 Service Bulletin 57–JA140140, Original Issue, dated June 26, 2014. For the purposes of this AD, owner/operators who do not track total FC must multiply the total number of airplane hours time-in-service (TIS) by 0.75 to calculate the cycles.

(2) If any crack or corrosion is found during any inspection required by paragraph (f)(1) of this AD, before further flight, contact BAE Systems (Operations) Ltd for FAA-approved repair instructions approved specifically for this AD and accomplish those instructions. You can find contact information for BAE Systems (Operations) Ltd in paragraph (i)(3) of this AD. Use the Operator Report Form and follow the instructions in British Aerospace Jetstream Series 3100 & 3200 Service Bulletin 57–JA140140, Original Issue, dated: June 26, 2014.

(3) Repair of an airplane as required in paragraph (f)(2) of this AD does not terminate the repetitive inspections required in paragraph (f)(1) of this AD for that airplane, unless the approved repair instructions state otherwise.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, 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: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: email: *doug.rudolph@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) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required

to assure the product is airworthy before it is returned to service.

(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 European Aviation Safety Agency (EASA) AD No.: 2015–0063, dated April 22, 2015, for related information. The MCAI can be found in the AD docket on the Internet at: *http://www.regulations.gov/#!documentDetail;D=FAA-2015-1744-0002*.

(i) 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) British Aerospace Regional Aircraft British Aerospace Jetstream Series 3100 & 3200 Service Bulletin 57–JA140140, Original Issue, dated: June 26, 2014.

(ii) Reserved.

(3) For British Aerospace Regional Aircraft service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone: +44 1292 675207; fax: +44 1292 675704; email: *RApublications@baesystems.com;* Internet: *http://www.baesystems.com/Businesses/RegionalAircraft/*.

(4) You may view this service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. In addition, you can access this service information on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–1744.

(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 August 6, 2015.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–19778 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–2048; Directorate Identifier 2015–CE–015–AD; Amendment 39–18230; AD 2015–16–05]

RIN 2120–AA64

Airworthiness Directives; British Aerospace Regional Aircraft Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for British Aerospace Regional Aircraft Jetstream Series 3101 and Jetsream Model 3201 airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as missing countersunk washers under the head of the main landing gear trunnion cap tension bolts that could cause fatigue in the bolt shanks. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective September 21, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of September 21, 2015.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2048; or in person at Document 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 service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone: +44 1292 675207; fax: +44 1292 675704; email: *RApublications@baesystems.com;* Internet: *http://www.baesystems.com/Businesses/RegionalAircraft/*. You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. You may view this referenced service information at the FAA, Small Airplane Directorate, 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 Docket No. FAA–2015–2048.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to adding an AD that would apply to British Aerospace Regional Aircraft Model Jetstream Series 3101 and Jetstream Model 3201 airplanes. The NPRM was published in the **Federal Register** on June 9, 2015 (80 FR 32510). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country.

The MCAI states:

> The review of the BAE production drawing for main landing gear (MLG) fitting installation identified a risk of omitting installation of a countersunk washer under the head of the MLG trunnion cap tension bolts, potentially causing fatigue in the bolt shank under the head of such tension bolt(s).
>
> This condition, if not detected and corrected, could lead to failure of the bolt(s), thereby compromising the structural integrity of the other MLG tension bolts holding the MLG in place, possibly resulting in collapse of the MLG on take-off or landing with consequent damage to the aeroplane and injury to occupants.
>
> Although so far, no in-service bolt head failures have been reported since entry in to service of the type design in 1986, to address this potential unsafe condition, BAE Systems (Operations) Ltd issued Service Bulletin (SB) 57–JA120141 to provide inspection instructions.
>
> For the reasons described above, this AD requires inspection and, depending on findings, replacement of the MLG trunnion cap tension bolts.

The MCAI can be found in the AD docket on the Internet at: *http://www.regulations.gov/*

#!documentDetail;D=FAA-2015-2048-0003.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (80 FR 32510, June 9, 2015) 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 the 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 (80 FR 32510, June 9, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 32510, June 9, 2015).

Related Service Information Under 1 CFR Part 51

We reviewed British Aerospace Regional Aircraft British Aerospace Jetstream Series 3100 & 3200 Service Bulletin 57–JA120141, REVISION 1, dated April 8, 2014. The service information describes procedures for inspection and replacement of main landing gear trunnion cap tension bolts. 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 of this AD.

Costs of Compliance

We estimate that this AD will affect 66 products of U.S. registry. We also estimate that it will take about 6 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of the AD on U.S. operators to be $33,660, or $510 per product.

In addition, we estimate that any necessary follow-on actions will take about 1 work-hour and require parts costing $1,200, for a cost of $1,285 per product. We have no way of determining the number of products that may need these actions.

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.

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, 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.

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–2015–2048; 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 the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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 AD:

2015–16–05 British Aerospace Regional Aircraft: Amendment 39–18230; Docket No. FAA–2015–2048; Directorate Identifier 2015–CE–015–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective September 21, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to British Aerospace Regional Aircraft Jetstream Series 3101 and Jetsream Model 3201 airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 32: Landing Gear.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as missing countersunk washers under the head of the main landing gear (MLG) trunnion cap tension bolts that could cause fatigue in the bolt shanks. We are issuing this AD to detect and correct missing countersunk washers, which could lead to failure of the bolt(s), thereby compromising the structural integrity of the other MLG tension bolts holding the MLG in place, possibly resulting in collapse of the MLG on take-off or landing with consequent damage to the airplane and injury to occupants.

(f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (f)(4) of this AD, including all subparagraphs, following the Accomplishment Instructions in British Aerospace Jetstream Series 3100 & 3200 Service Bulletin 57–JA120141, REVISION 1, dated April 8, 2014:

(1) This AD allows credit for the actions required in paragraphs (f)(3) and (f)(4), including all subparagraphs, of this AD if done before September 21, 2015 (the effective date of this AD) following the Accomplishment Instructions of British Aerospace Jetstream Series 3100 & 3200 Service Bulletin 57–JA120141, Original Issue, dated: July 31, 2012.

(2) For the purposes of this AD, owner/operators who do not track total flight cycles (FC) must multiply the total number of airplane hours time-in-service by 0.75 to calculate the FC.

(3) *For Pre-Mod JM5218 airplanes:* Within 250 FC after September 21, 2015 (the

effective date of this AD), do a magnetic particle inspection (MPI) of each MLG trunnion cap tension bolt.

(i) If no crack is found during the MPI required by paragraph (f)(1) of this AD, before further flight, either re-install the crack-free bolt(s) or install a replacement bolt(s) having the same part number (P/N) as the original bolt. Install a countersunk washer under the bolt(s) ensuring the washer P/N is applicable to the diameter bolt installed as specified in figure 1 of paragraph (f)(3)(i) of this AD.

FIGURE 1 OF PARAGRAPH (f)(3)(i)—PRE-MOD JM5218 REPLACEMENT PARTS

Bolt P/N	Washer P/N
MS21250H06040	PKS1000–6–2–S (washer).
MS21250H07040	PKS1000–7–2–S (washer).

(ii) If a cracked bolt is found during the inspection required by paragraph (f)(3) of this AD, before further flight, replace each cracked bolt with a replacement bolt having the same P/N as the original bolt. Install a countersunk washer under the bolt ensuring the washer P/N is applicable to the diameter bolt installed as specified in figure 1 of paragraph (f)(3)(i) of this AD.

(4) *For Post-Mod JM5218 airplanes:* Within 250 FC after September 21, 2015 (the effective date of this AD), visually inspect each MLG trunnion cap tension bolt to determine which type of bolt is installed.

(i) If it is determined the installed bolts are P/N MS21134H07045 or P/N MS21134H07059 during the inspection required in paragraph (f)(4) of this AD, before further flight (except as specified in paragraph (f)(4)(i)(A) of this AD), replace each 'old' bolt P/N with a 'new' bolt P/N as specified in figure 2 of paragraph (f)(4)(i) of this AD and install a washer having P/N PKS1000–7–2–S under each bolt.

FIGURE 2 OF PARAGRAPH (f)(4)(i)—POST-MOD JM5218 REPLACEMENT PARTS

Bolt P/N 'Old'	Bolt P/N 'New'
MS21134H07045	MS21134H07046, or MS21250H07046.
MS21134H07059	MS21134H07060, or MS21250H07060.

(A) If no 'new' replacement bolt is available to comply with paragraph (f)(4)(i) of this AD, the 'old' bolt may be reinstalled without a countersunk washer, provided that within 500 FC after reinstallation and repetitively thereafter at intervals not to exceed 500 FC, each affected bolt is inspected by MPI.

(B) Within 2,000 FC after reinstallation of a bolt as allowed by paragraph (f)(4)(i)(A) of this AD or before further flight if a crack was found during any MPI as required by paragraph (f)(4)(i)(A) of this AD, whichever occurs first, replace the 'old' bolt P/N with a 'new' bolt P/N as specified in figure 2 of paragraph (f)(4)(i) of this AD and install a washer having P/N PKS1000–7–2–S under each bolt.

(ii) If it is determined the installed bolts are P/N MS21250H07046 or P/N MS21250H07060 and no countersunk washer is installed during the inspection required in paragraph (f)(4) of this AD, before further flight, do an MPI of each MLG trunnion cap tension bolt.

(A) If no crack is found during the MPI required by paragraph (f)(4)(ii) of this AD, before further flight, either re-install the crack-free bolts or install replacement bolts having a 'new' bolt P/N as specified in figure 2 of paragraph (f)(4)(i) of this AD and install a countersunk washer P/N PKS1000–7–2–S under each bolt.

(B) If any crack is found during the MPI required by paragraph (f)(4)(ii) of this AD, before further flight, replace each cracked bolt with a serviceable one having a 'new' bolt P/N as specified in figure 2 of paragraph (f)(4)(i) of this AD and install a countersunk washer P/N PKS1000–7–2–S under each bolt.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, 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: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@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) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2015–0061, dated April 20, 2015; and British Aerospace Jetstream Series 3100 & 3200 Service Bulletin 57–JA120141, Original Issue, dated: July 31, 2012, for related information. The MCAI can be found in the AD docket on the Internet at: *http://www.regulations.gov/#!documentDetail;D=FAA-2015-2048-0003*.

(i) 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) British Aerospace Jetstream Series 3100 & 3200 Service Bulletin 57–JA120141, REVISION 1, dated April 8, 2014.

(ii) Reserved.

(3) For British Aerospace Regional Aircraft service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone: +44 1292 675207; fax: +44 1292 675704; email: *RApublications@baesystems.com;* Internet: *http://www.baesystems.com/Businesses/RegionalAircraft/*.

(4) You may view this service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. In addition, you can access this service information on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2048.

(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 August 6, 2015.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–19776 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2014–0639; Airspace Docket No. 13–ASW–20]

RIN 2120–AA66

Modification of Restricted Areas R–3804A, R–3804B, and R–3804C; Fort Polk, LA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action expands the lateral boundary of restricted area R–3804B, Fort Polk, LA, and raises the restricted area ceiling to, but not including 10,000 feet mean sea level (MSL). The expanded restricted area airspace will contain new live fire ranges to support mission requirements of the U.S. Army in order to fully exploit the capabilities of modern weapons systems and complex training scenarios that replicate conditions encountered during military deployments today. This action also amends time of designation for R–3804A and R–3804B to better reflect when the restricted areas are in use by the U.S. Army and when the airspace is available to nonparticipants. Lastly, this action makes administrative editorial

corrections to the R–3804A, R–3804B, and R–3804C legal descriptions.

DATES: Effective date: 0901 UTC, October 15, 2015.

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

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 the 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 restricted area airspace at Fort Polk, LA, to enhance aviation safety and accommodate essential U.S. Army training requirements.

History

On September 25, 2014, the FAA published in the **Federal Register** a notice of proposed rulemaking (79 FR 57486) to expand the lateral boundary and raise the designated altitudes of restricted area R–3804B, amend the time of designation for R–3804A and R–3804B, and make using agency corrections to R–3804A, R–3804B, and R–3804C. The R–3804 restricted area complex amendments support the military training activities conducted at Fort Polk, LA.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. Fifteen comments were received with 14 of the commenters supporting the proposed action, and one commenter raising several concerns.

The commenter suggested the FAA offset a larger R–3804B by eliminating the R–3801A, R–3801B, and R–3801C restricted areas and/or the R–3803A and R–3803B restricted areas. The commenter offered that since the R–3801 complex and the Hackett and Jena Military Operations Areas (MOAs) all have the deactivated 917th Fighter Wing listed as the using agency, the FAA should consider them for deactivation. The R–3801 complex and associated MOAs mentioned by the commenter are used by U.S. Air Force B–52 aircraft operating from Barksdale Air Force Base (AFB), LA, for electronic combat training. The FAA has amended the legal descriptions of these Special Use Airspace (SUA) areas, effective April 30, 2015, to reflect the current using agency, the 307th Bomb Wing at Barksdale AFB, LA. The R–3803 complex noted by the commenter is used by U.S. Army units at Fort Polk for live fire training similar to that occurring in the R–3804 complex. The actual time the restricted area complexes are activated is roughly the same and consistent with the expected usage of the proposed R–3804B.

The commenter also stated that real-time deactivation of the restricted area complex during Notice to Airmen (NOTAM) periods of use is a disservice to civilian pilots who have flight planned to avoid the airspace. In the interest of maximizing navigable airspace availability to the flying public, the FAA considers real-time deactivation of SUA airspace, and making it available to non-participants, an efficient use of the National Airspace System. Under the FAA ''joint use'' concept, SUA is expected to be released to the controlling agency and become available for access by nonparticipating aircraft during periods when the airspace is not needed by the using agency for its designated purpose.

Lastly, the commenter questioned how much of the NOTAM activation period is actually going to be used by Fort Polk. The expected usage of R–3804B is approximately 2 weeks per month, continuously, during large unit training rotations. Modern weapons capabilities and tactics are optimized for around-the-clock employment, and training events to replicate combat scenarios can occur any time of the day or night. The R–3804 complex utilization reporting for 2013, the most recent year available, shows R–3804B to have been activated 5,412 hours out of a possible 8,760 hours. The FAA considers this utilization rate to be consistent with Fort Polk's planned use of the proposed R–3804B.

The amendments to R–3804A, R–3804B, and R–3804C are addressed below.

The Rule

This action amends Title 14, Code of Federal Regulations (14 CFR) part 73 by expanding the lateral and vertical dimensions of restricted area R–3804B, Fort Polk, LA; changing the times of designation for R–3804A and R–3804B; and updating the using agency information for R–3804A, R–3804B, and R–3804C, and removing unnecessary verbiage from the designated altitudes and times of designation information for R–3804C.

The R–3804B boundary is expanded northward to match the northern boundary of R–3804A, as described in the NPRM, and the designated altitudes are raised from 3,000 feet MSL to, but not including, 10,000 feet MSL. This lateral and vertical expansion of R–3804B ensures containment of the hazardous artillery and mortar fires planned by the U.S. Army.

Additionally, the time of designation for R–3804A and R–3804B are changed from ''Continuous'' to ''By NOTAM.'' This amendment ensures the restricted areas are available to the U.S. Army when needed, continuously approximately two weeks each month, and provides a better indication to nonparticipants when the restricted areas are active and when they are available for use by the public.

Lastly, this action makes editorial updates to the using agency name for R–3804A, R–3804B, and R–3804C to incorporate the military service component of the using agency in the using agency name, removes the word ''up'' contained in the designated altitudes for R–3804C, and removes the words ''As published'' contained in the time of designation for R–3804C. These are purely administrative changes that do not affect the scheduling, use, or activities conducted within the restricted areas.

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. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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

Regarding expansion of the lateral boundary and raising the designated altitudes of restricted area R–3804B, in

accordance with FAA Order 1050.1E, paragraphs 402 and 404d, the FAA has conducted an independent evaluation of the United States Army, Joint Readiness Training Center's Final Environmental Assessment for the Establishment of Additional Restricted Airspace Joint Readiness Training Center and Fort Polk, LA dated March 2013 (hereinafter ''the FEA''). The FAA adopted the relevant portions of the FEA and prepared a Finding of No Significant Impact/Record of Decision dated August 11, 2015. The FAA has determined that no significant impacts would occur as a result of the Federal action and therefore that preparation of an Environmental Impact Statement is not warranted, and a Finding of No Significant Impact in accordance with 40 CFR part 1501.4(e) is appropriate.

Regarding amending the time of designation for R–3804A and R–3804B, the FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, Environmental Impacts: Policies and Procedures, paragraph 311c. This action, by changing time of designation from ''continuous'' to ''by NOTAM'' serves to return all or part of special use airspace (SUA) to the National Airspace System (NAS). It is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exists that warrant preparation of an environmental assessment.

Regarding making using agency corrections to R–3804A, R–3804B, and R–3804C, the FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, Environmental Impacts: Policies and Procedures, paragraph 311d. This action is an administrative change to the titles in the descriptions of the affected restricted areas to reflect the correct locations. It does not alter the dimensions, altitudes, times of designation or actual physical locations of the airspace; therefore, it is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exists that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

Adoption of the Amendment

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

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 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.

§ 73.38 [Amended]

■ 2. Section 73.38 is amended as follows:

* * * * *

R–3804A Fort Polk, LA (Amended)

Boundaries. Beginning at lat. 31°00′53″ N., long. 93°08′12″ W.; to lat. 31°00′53″ N., long. 92°56′53″ W.; to lat. 31°00′20″ N., long. 92°56′14″ W.; to lat. 31°00′20″ N., long. 92°54′23″ W.; to lat. 31°03′55″ N., long. 92°51′34″ W.; to lat. 31°09′35″ N., long. 92°58′25″ W.; to lat. 31°09′35″ N., long. 93°00′56″ W.; to lat. 31°08′43″ N., long. 93°01′55″ W.; to lat. 31°08′43″ N., long. 93°08′12″ W.; to the point of beginning.

Designated altitudes. Surface to FL 180.

Time of designation. By NOTAM.

Controlling agency. FAA, Houston ARTCC.

Using agency. U.S. Army, Commanding General, Fort Polk, LA.

R–3804B Fort Polk, LA (Amended)

Boundaries. Beginning at lat. 31°00′53″ N., long. 93°10′53″ W.; to lat. 31°00′53″ N., long. 93°08′12″ W.; to lat. 31°08′43″ N., long. 93°08′12″ W.; to lat. 31°08′43″ N., long. 93°11′00″ W.; to lat. 31°04′56″ N., long. 93°11′00″ W.; to lat. 31°04′15″ N., long. 93°12′31″ W.; to the point of beginning.

Designated altitudes. Surface to but not including 10,000 feet MSL.

Time of designation. By NOTAM.

Controlling agency. FAA, Houston ARTCC.

Using agency. U.S. Army, Commanding General, Fort Polk, LA.

R–3804C Fort Polk, LA (Amended)

Boundaries. Beginning at lat. 31°00′53″ N., long. 93°08′12″ W.; to lat. 31°00′53″ N., long. 92°56′53″ W.; to lat. 31°00′20″ N., long. 92°56′14″ W.; to lat. 31°00′20″ N., long. 92°54′23″ W.; to lat. 31°03′55″ N., long. 92°51′34″ W.; to lat. 31°09′35″ N., long. 92°58′25″ W.; to lat. 31°09′35″ N., long. 93°00′56″ W.; to lat. 31°08′43″ N., long. 93°01′55″ W.; to lat. 31°08′43″ N., long. 93°08′12″ W.; to the point of beginning.

Designated altitudes. FL 180 to but not including FL 350.

Time of designation. By NOTAM 24 hours in advance.

Controlling agency. FAA, Houston ARTCC.

Using agency. U.S. Army, Commanding General, Fort Polk, LA.

Issued in Washington, DC, on August 11, 2015.

M. Randy Willis,

Acting Manager, Airspace Policy and Regulations Group.

[FR Doc. 2015–20286 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2015–N–2737]

Medical Devices; Neurological Devices; Classification of the Computerized Cognitive Assessment Aid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the computerized cognitive assessment aid into class II (special controls). The special controls that will apply to the device are identified in this order, and will be part of the codified language for the computerized cognitive assessment aid's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective September 16, 2015. The classification was applicable on June 5, 2015.

FOR FURTHER INFORMATION CONTACT: Peter Como, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G242, Silver Spring, MD 20993–0002, 301–796–6919, *peter.como@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendment devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially

equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On June 24, 2013, Cerebral Assessment Systems, Inc., submitted a request for classification of the Cognivue under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 5, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 882.1470.

Following the effective date of this final classification administrative order, any firm submitting a premarket notification [510(k)] for a computerized cognitive assessment aid will need to comply with the special controls named in the final order. The device is assigned the generic name computerized cognitive assessment aid, and it is identified as a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The computerized cognitive assessment aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical diagnoses. The computerized cognitive assessment aid is not intended as a stand-alone or adjunctive diagnostic device.

FDA has identified the following risks to health associated specifically with this type of device, as well as the measures required to mitigate these risks in table 1:

TABLE 1—COMPUTERIZED COGNITIVE ASSESSMENT AID RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Equipment malfunction leading to subject injury (shock, burn, or mechanical failure)	Electrical safety testing. Labeling.
User discomfort (*e.g.*, visual fatigue, stimulus-induced nausea)	Labeling.
Incorrect result, inclusive of: • False positive—cognitive impairment when, in fact, none is present • False negative—cognitive impairment when, in fact, cognitive impairment is present	Hardware and software verification, validation, and hazard analysis. Labeling.

FDA believes that the following special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

- The technical parameters of the device's hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:
  - Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.
  - Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's cognitive function, must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.
- The device must be designed and tested for electrical safety.
- The labeling must include:
  - A summary of any testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function. The summary of testing must include the following, if available: Any expected or observed adverse events and complications; any performance measurements including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) per the device intended use; a description of the repeatability of measurements; a description of how the cut-off values for categorization of measurements were determined; and a

description of the construct validity of the device.

○ A warning that the device does not identify the presence or absence of clinical diagnoses.

○ A warning that the device is not a stand-alone diagnostic.

○ The intended use population and the intended use environment.

○ Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

Computerized cognitive assessment aids are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the computerized cognitive assessment aid they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov*.

1. DEN130033: De Novo Request per 513(f)(2) of the Federal Food, Drug, and Cosmetic Act from Cerebral Assessment Systems, Inc., dated June 24, 2013.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 882.1470 to subpart B to read as follows:

§ 882.1470 Computerized cognitive assessment aid.

(a) *Identification.* The computerized cognitive assessment aid is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The computerized cognitive assessment aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical diagnoses. The computerized cognitive assessment aid is not intended as a stand-alone or adjunctive diagnostic device.

(b) *Classification.* Class II (special controls). The special control(s) for this device are:

(1) The technical parameters of the device's hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's cognitive function, must be described in detail in the software requirements specification (SRS) and software design specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.

(2) The device must be designed and tested for electrical safety.

(3) The labeling must include:

(i) A summary of any testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function. The summary of testing must include the following, if available: Any expected or observed adverse events and complications; any performance measurements including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) per the devices intended use; a description of the repeatability of measurements; a description of how the cut-off values for categorization of measurements were determined; and a description of the construct validity of the device.

(ii) A warning that the device does not identify the presence or absence of clinical diagnoses.

(iii) A warning that the device is not a stand-alone diagnostic.

(iv) The intended use population and the intended use environment.

(v) Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

Dated: August 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20177 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 35

[Public Notice 9220]

RIN 1400–AD85

Program Fraud Civil Remedies

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is updating its regulations regarding its implementation of the Program Fraud Civil Remedies Act of 1986, to remove a conflict between the ''reviewing official'' and the ''authority head'' as defined by the implementing regulations.

DATES: This rule is effective August 17, 2015.

FOR FURTHER INFORMATION CONTACT: Alice Kottmyer, Attorney-Adviser,

Office of the Legal Adviser, (202) 647–2318, or *kottmyeram@state.gov.*

SUPPLEMENTARY INFORMATION: The Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 *et seq.* (the Act), outlines a procedure for establishing administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false fictitious, or fraudulent claims or written statements to authorities or to their agents; and specifying the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments. In a nutshell, the ''investigating official'' (who is in the Office of the Inspector General) presents a case to the ''reviewing official'' (currently defined as the Chief Financial Officer) who, if appropriate, forwards the case to the Department of Justice. The Department of Justice will approve a ''claim'' if it believes further action is warranted. The reviewing official serves the claim on the respondent. There is a hearing before an administrative law judge (ALJ), and a disposition adverse to the respondent can be appealed to the ''authority head,'' defined in the rule as the Under Secretary for Management.

Currently, the Under Secretary for Management is designated by the President as the Chief Financial Officer for the Department of State. Therefore, he is the reviewing official as well as the authority head, which of course is unacceptable. This rule corrects that anomaly, by defining the ''reviewing official'' as the Assistant Legal Adviser for Buildings and Acquisitions (hereinafter, ''the ALA''). The Under Secretary for Management remains the authority head.

The Act (in 31 U.S.C. 3801(a)(8)) outlines the qualifications for the reviewing official, all of which are met by the ALA. (1) He or she must be designated by the authority head to make the determination under 31 U.S.C. 3803(a)(2) to send the case to the Department of Justice for its review and action, if appropriate. (2) He or she must be serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS–16 under the General Schedule; the ALA is a member of the Senior Executive Service, and thus has a rate of pay at least as high as GS–16, a grade which was eliminated under the provisions of the Civil Service Reform Act of 1978. (3) He or she must not be subject to supervision by, or required to report to, the investigating official, and not employed in the organizational unit of the authority in which the investigating official is employed; the ALA is not in the Office of the Inspector General and is not (nor will he or she ever be) subject to the supervision of anyone in that office.

Accordingly, 22 CFR 35.2(r), the definition of ''reviewing official,'' is changed by this rulemaking.

Regulatory Findings

Administrative Procedure Act

This regulation amends a ''rule of agency organization, procedure, or practice'', which is not subject to the notice-and-comment rulemaking procedures set forth in 5 U.S.C. 553. See 5 U.S.C. 553(b). Therefore, the Department is issuing this amendment as a final rule.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth by the Regulatory Flexibility Act. Nonetheless, consistent with the Regulatory Flexibility Act, the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by 5 U.S.C. 804. The Department is aware of no monetary effect on the economy that would result from this rulemaking, nor will there be any increase in costs or prices; or any effect on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and import markets.

Executive Orders 12866 and 13563

The Department of State has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Orders 12866 and 13563, and has determined that the benefits of this regulation outweigh any cost. The Department does not consider this rule to be a economically significant rulemaking action.

Executive Orders 12372 and 13132: Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. The rule will not have federalism implications warranting the application of Executive Orders 12372 and 13132.

Executive Order 12988: Civil Justice Reform

The Department has reviewed the regulation in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

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

Paperwork Reduction Act

This rule does not impose or revise information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 35

Administrative practice and procedure, Claims, Fraud, Penalties.

For the reasons stated in the preamble, amend part 35 of title 22 of the Code of Federal Regulations as follows:

PART 35—PROGRAM FRAUD CIVIL REMEDIES

■ 1. The authority citation for part 35 is revised to read as follows:

Authority: 22 U.S.C. 2651a; 31 U.S.C. 3801 *et seq.*

■ 2. Revise § 35.2(r) to read as follows:

§ 35.2 Definitions.

* * * * *

(r) *Reviewing official* means the Assistant Legal Adviser for Buildings and Acquisitions or her or his designee who is—

(1) Not subject to supervision by, or required to report to, the investigating official;

(2) Not employed in the organizational unit of the authority in which the investigating official is employed; and

(3) Serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS–16 under the General Schedule.

* * * * *

Dated: August 3, 2015.

Patrick F. Kennedy,

Under Secretary of State for Management, Department of State.

[FR Doc. 2015–20263 Filed 8–14–15; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 15

[Docket No. FR–5624–F–02]

RIN 2501–AD57

Revision of Freedom of Information Act Regulation

AGENCY: Office of the Deputy Secretary, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends HUD's regulations implementing the Freedom of Information Act (FOIA) to update and streamline HUD's current FOIA regulation. Specifically, it updates HUD's regulations to reflect statutory changes to the FOIA, current HUD organizational structure, and current HUD policies and practices with respect to the FOIA. In addition, the rule uses current cost figures in calculating and charging fees. This final rule also incorporates changes made upon further evaluation of HUD's FOIA Regulation and in response to public comments received.

DATES: *Effective:* September 16, 2015.

FOR FURTHER INFORMATION CONTACT: Dolores W. Cole, Director, FOIA and Executive Correspondence, Office of Administration, Department of Housing and Urban Development, 451 7th Street SW., Room 10139, Washington, DC 20410–0500; telephone number 202–402–2671 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the Federal Relay Service at telephone number 1–800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

HUD's regulations at 24 CFR part 15 contain the policies and procedures governing public access to HUD records under the FOIA (5 U.S.C. 552). Subject to certain statutory exceptions, the FOIA gives persons the right to request and receive a wide range of information from any Federal agency. The FOIA has been amended several times since its enactment in 1966. In 2007, significant amendments to the FOIA were made by the Openness Promotes Effectiveness in our National Government Act of 2007 (OPEN Government Act) (Pub. L. 110–175, approved December 31, 2007). The OPEN Government Act made several amendments to procedural issues affecting FOIA administration, including the protection of the fee status for news media, the time limits for agencies to act upon FOIA requests, the availability of agency records maintained by a private entity, the establishment of a FOIA Public Liaison and FOIA Requester Service Center, and the requirement to describe the exemptions authorizing the redaction of material provided under the FOIA.

In addition to these statutory changes, several policy directives have been issued that affect HUD's FOIA program. These policy directives include Presidential memoranda dated January 21, 2009, entitled ''Freedom of Information Act'' (74 FR 4683, January 26, 2009), which applies a presumption of disclosure in FOIA decision-making and ''Transparency and Open Government'' (74 FR 4685, January 26, 2009), which encourages Federal agencies to harness new technologies to proactively post online information about their operations and decisions consistent with applicable law. As required by the Presidential memoranda, on March 19, 2009, Attorney General Eric Holder issued comprehensive new FOIA guidelines (see *http://www.justice.gov/ag/foia-memo-march2009.pdf*). The Attorney General's guidance further advises that agencies should release information to the fullest extent of the law, including information that may be legally withheld, provided there is no foreseeable harm to an interest protected by an exemption or the disclosure is not prohibited by law. In addition, the Attorney General's FOIA guidelines emphasized that agencies must have effective systems in place for responding to FOIA requests.

Consistent with this law and guidance, HUD undertook a comprehensive review of its FOIA regulation. As part of this review, HUD looked to the proposed updated FOIA regulation published by the Department of Justice (DOJ) on March 21, 2011 (76 FR 15236). DOJ intended that its regulation serve as a model for all agencies in updating their own FOIA regulations.[1] As a result of its review, HUD published a proposed rule on May 31, 2013 (78 FR 32595), modeled on DOJ's proposed regulation, to incorporate changes enacted by the OPEN Government Act of 2007, reflect developments in case law, include current cost figures for calculating and charging fees, and enhance the administration and operation of HUD's FOIA program by increasing the transparency and clarity of the regulation.

II. Changes and Clarifications Made in This Final Rule

This final rule follows publication of the May 31, 2013, proposed rule and takes into consideration the public comments received on the proposed rule. In response to public comment, a discussion of which is presented in the following section of this preamble, and in further consideration of issues addressed at the proposed rule stage, the Department is making the following changes at this final rule:

- HUD is revising § 15.103(c) to state that HUD will provide written notice to requesters when the time limits for HUD's response will be delayed. HUD will also provide the requester with the date by which HUD expects to complete its processing of the request.
- HUD is revising § 15.104(c)(3) to mirror the language of the FOIA. Specifically, HUD is removing the requirement that a representative of the news media, if not a full-time member of the news media, should establish that he or she is a person whose main professional activity or occupation is information dissemination.
- HUD is revising § 15.106(c) to reduce the duplication costs that HUD will charge for a paper photocopy of a record from $0.18 per page to $0.10 per page.
- HUD is revising § 15.107(a) to refer to the most current Executive order regarding classified information, which is Executive Order 13526, issued December 29, 2009.
- HUD is removing proposed § 15.109 from this final rule. Upon review HUD has determined that, § 15.109, entitled ''Mortgage sales,'' directed itself to a specific HUD program rather than establish disclosure policy applicable

[1] See, *http://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/03/15/11/03-15-11-oip-pustay-testimony-re-the-freedom-of-information-act---ensuring-transparency-and-accountability-in-the-digital-age.pdf.*

throughout the Department. In addition, § 15.109 as proposed did not accurately describe the process that HUD uses to address FOIA requests for information arising out of HUD's mortgage sales program. As a result, HUD is removing § 15.109 as proposed from this final rule.

- HUD is revising § 15.110(a) of the proposed rule (redesignated as § 15.109(a) in this final rule) to clarify that appeals may be submitted electronically.
- HUD is revising § 15.111(a)(2) of the proposed rule (redesignated as § 15.110(a)(2) in this final rule) by adding paragraph (iii) to provide that HUD will notify requesters of dispute resolution services in its FOIA appeal determination response letter.

III. Analysis of Public Comments

The public comment period for the May 31, 2013, proposed rule closed on July 30, 2013, and HUD received three public comments on the proposed rule. Comments were submitted by a nonprofit organization devoted to issues of effective government and by two members of the public. HUD reviewed the comments and considered responses to them. This section presents the significant issues, questions, and suggestions submitted by the commenters and HUD's responses.

Comment: HUD should expand online disclosures. One commenter recommended that HUD adopt a policy of proactively identifying records that are of interest to the public and posting such records online without waiting for FOIA requests. Accordingly, the commenter recommended that § 15.101 be revised to state that ''HUD will proactively identify and disclose additional records of interest to the public.'' The commenter added that the E–FOIA Act of 1996 mandates agencies to post online any information that has been released in response to a FOIA request and ''is likely to become the subject of subsequent requests.'' The commenter stated that some agencies have adopted the practice of posting all released records and suggested that HUD adopt this policy by revising its proposed rule to read: ''HUD will post all records released in response to FOIA requests in a searchable format on the agency Web site.'' Finally, the commenter stated that HUD should also revise § 15.101 by adopting a policy of publishing online its indexes of disclosed records.

Response: Section 15.101 revises HUD's FOIA regulation to reflect its current practice of proactively identifying and disclosing frequently requested records without waiting for a FOIA request. HUD developed the list of documents that it posts without request based on its prior experience regarding agency records that generally are of interest to the public. This list is not exhaustive and the final rule provides HUD the flexibility to post additional records without request. Releasing all records requested, along with an index, as requested by the commenter, would be excessively burdensome for the agency. HUD believes that § 15.101, as drafted, successfully balances its commitment to transparency as directed by President Obama's memorandum and Attorney General Holder's FOIA Guidance, within the scope of HUD's available resources. Accordingly, HUD has determined not to revise this section as the commenter recommended.

Comment: Information about the record sought. A commenter stated that clear and open communications between requesters and agency staff is vital to an effective, user-friendly FOIA process. Toward this end, the commenter recommended that HUD revise § 15.102(d)(2) to delete the first sentence that provides that FOIA requests ''include, whenever possible, detailed and specific information about each record sought, such as the date, title or name, author, recipient, and subject matter of the record,'' and substitute simply that FOIA requests should ''reasonably describe the records sought.'' The commenter also recommended that HUD delete the last sentence of this paragraph, which reads ''Insufficient descriptions may lead HUD officials to contact the requester to seek additional information for their record search.''

Response: HUD agrees that clear and open communications is vital to an effective and user-friendly FOIA process. Based on HUD's experience, § 15.102(d)(2) supports this goal by describing the type of information that will assist HUD to more promptly and effectively respond to a FOIA request. HUD therefore declines to revise § 15.102(d)(2) as suggested by the commenter.

Comment: Notification of further clarification needed. A commenter stated that HUD should adopt a policy stating that it will contact the requester to seek clarification before denying a request on the basis of its not reasonably describing the records sought. The commenter suggested that HUD revise this section of the rule to state: ''If HUD believes that a request may not reasonably describe the records sought, HUD will contact the requester to seek clarification. HUD will provide at least 30 days for the requester to respond. If the request has not been clarified after 30 days, HUD may decide to deny the request for not reasonably describing the records sought. If HUD determines that it must deny the request for not reasonably describing the records sought, it will notify the requester under the procedures in § 15.105(d)(2).''

Response: HUD's current policy is to request clarification prior to issuing an adverse determination based on a requester's failure to reasonably describe the records sought. In addition, depending on the specific request, HUD may on a case-by-case basis establish time limits for the requester to provide clarification. HUD, therefore, believes that imposing a 30-day time period would unnecessarily limit the staff's ability to exercise discretion in processing these requests. HUD, therefore, declines to revise § 15.105(d)(2) as recommended by the commenter.

Comment: Notification of delayed processing. A commenter recommended that HUD revise § 15.103(c) to state that HUD will notify requesters in writing as is required by FOIA when processing will be delayed.

Response: HUD agrees with the commenter and revises § 15.103(c) of the final rule to mirror the language of the FOIA by providing that, in unusual circumstances, the time limits prescribed in the regulation may be extended by written notice to the requester making such request. The written notice will also set forth the unusual circumstances for such extension and the date on which a determination is expected to be released.

Comment: Phrasing of revised language in § 15.104(c)(3). A commenter stated that language in proposed § 15.104(c)(3), which would require requesters who are not full-time members of the news media to submit a statement establishing that the requester ''is a person whose main professional activity or occupation is information dissemination'' when requesting expedited processing of a request, changes the meaning of FOIA. According to the commenter, this requirement is not found in FOIA and excludes an entire class of individuals, such as bloggers and other participants and thought leaders of the digital world who may be well positioned to expedite dissemination of information. The commenter recommended that the reference to ''main professional activity or occupation'' be removed and that § 15.104(c)(3) be revised to mirror FOIA.

Response: HUD agrees that the language in the final rule should mirror the language in the FOIA and therefore revises § 15.104(c)(3) to require that the

requester be ''primarily engaged in disseminating information.'' References to requirements that the requester, ''if not a full-time member of the news media, should establish that he or she is a person whose main professional activity or occupation is information dissemination,'' have been deleted.

Comment: Notification of rerouting and referrals. Two commenters recommended that HUD revise the rule to improve communications with the requester. These commenters recommended that HUD notify the requester if it reroutes the request to another government agency or second HUD office, as is permitted during the 10-day window immediately following HUD's receipt of the initial FOIA request. The commenters described this change as a modest step that is consistent with the policies of other Federal agencies and which would benefit HUD by reducing the number of requester inquiries made to the HUD FOIA office.

Response: HUD's current policy is to notify requesters that their request is being rerouted or referred to another Federal agency or a second HUD office. Federal agencies to which requests are referred follow their own policies to ensure that requesters are notified that their FOIA requests have been received. In addition, requesters can identify the HUD FOIA office to which their request has been rerouted by checking the status of their request online at *http://www.hud.gov/FOIA.* Because these options are available to requesters, HUD declines to revise § 15.105 to adopt the commenters' recommendations.

Comment: Keeping requesters informed regarding updates on the status of their FOIA requests. A commenter recommended that HUD revise § 15.105 to include provisions that would require HUD to notify all requesters as soon as practicable of the estimated time it will take to complete a request and provide requesters with the opportunity to reformulate their requests. The commenter also recommended that HUD revise the rule to provide on the agency's Web site automated updates on the status of FOIA requests and suggested that HUD can implement this recommendation by joining the multiagency portal FOIA online, which allows requesters to track the status of requests online.

Response: Section 15.103(a) provides that HUD generally will respond to a FOIA request within 20 working days of receipt. As discussed in this preamble, HUD is revising this section in the final rule to state that it will provide written notice to requesters when it extends the time to process a request, and will also provide the requester with the date by which HUD expects to complete its processing of the request. Given the number, unpredictability, and variability in type and scope of FOIA requests that HUD receives, however, it would be extremely difficult for HUD to offer specific dates by which it could estimate the processing time for any specific FOIA request not subject to § 15.103(a). In addition, HUD provides requesters the ability to verify the status of their FOIA requests through an online tool that is similar to FOIAonline and that is available at *http://www.hud.gov/FOIA.* Finally, HUD believes that the rule already addresses the commenter's concern that requesters be granted an opportunity to reformulate requests during the process. For example, § 15.103(c) provides that HUD will offer the requester the opportunity to limit the scope of a request if HUD determines that providing responsive documents will take more than the 10 working days established in § 15.103(a). For these reasons, HUD declines to revise the rule as recommended by the commenter.

Comment: Electronic communications. A commenter recommended that HUD adopt a policy to communicate with requesters by email, where appropriate, as digital communications are changing the way government connects with citizens, and email communications could result in cost savings for the agency.

Response: The FOIA does not require agencies to use a specific means to communicate with requesters. HUD currently communicates with requesters by email, when appropriate, and will continue to do so. At the same time, HUD requires the discretion to use physical mail when it deems necessary. For these reasons, HUD declines to revise the rule as recommended by the commenter.

Comment: Plain communications. A commenter stated that the Plain Writing Act of 2010 directs agencies to use ''writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience'' in any document that ''provides information about Federal Government benefit or service.'' The commenter recommended that HUD revise § 15.105 to state: ''HUD will use plain language in all communications with requesters.''

Response: HUD's current policy is to use plain language for all communications with the public. Some requests, however, require the production of records that are inherently technical or drafted for audiences with more technical backgrounds or expertise than the general public. As a result, HUD concludes that adding the language suggested by the commenter would be superfluous and may mislead requesters to expect HUD to translate technical documents into plain language. HUD therefore declines to amend this section in the final rule as requested by the commenter.

Comment: Release records on a rolling basis. A commenter stated that HUD should revise § 15.105 to require HUD to release records on a rolling basis, where requests involve a voluminous amount of material or searches in multiple locations.

Response: HUD's existing policy allows individual HUD FOIA offices to decide whether to release voluminous amounts of records on a rolling basis or all at once, depending on the specific request, the difficulty of collecting records responsive to the request, and the effective administration of the office's internal FOIA processing. HUD declines to revise this section of the rule in order to permit individual HUD FOIA offices the continued discretion over the appropriate approach to releasing records.

Comment: Rate of per-page printing. Two commenters stated that HUD's fee of $0.18 per page is a potential impediment to requests from members of the public, that it is higher than the rate imposed by other agencies, and that it does not reflect the amount that it costs HUD to print on a page. Both commenters recommended that HUD establish a standard fee of $0.10 per page. In addition, one commenter recommended that HUD revise the regulation to provide that it will not charge a fee if the total fee does not exceed $50, instead of the $25 threshold proposed by § 15.106(d)(4). The commenter stated that charging requesters the costs for producing small FOIA requests is uneconomical and contributes to processing delays. The commenter also stated that revising the $25 threshold would streamline the processing of requests that cost HUD less than $50.

Response: HUD appreciates the commenters' recommendations. HUD has reviewed its FOIA fee structure and agrees that it should revise its longstanding policy of charging $0.18 per page to the standard fee of $0.10 per page. Section 15.106(c) is revised to reflect this change. HUD's cost of responding to a request, however, has not changed. As a result, HUD will continue its practice of not charging the requester for processing a request if the total fee does not exceed $25. Based on HUD's experience, even at this $25

threshold, most requesters will still not be charged a processing fee.

Comment: Fee Waivers. A commenter stated that the proposed § 15.106(k)(5), which would give HUD discretion to consider ''the cost effectiveness of its investment of administrative resources'' when deciding whether to grant requests for a fee waiver or reduction, contradicts the plain language of FOIA. The commenter asserted that FOIA provides that agencies do not have authority to consider additional factors when deciding to waive or reduce fees if the statutory conditions are met. Accordingly, the commenter recommended that § 15.106(k)(5) be struck from the final rule.

Response: Section 552(a)(4)(A)(i) of the FOIA states that, ''[i]n order to carry out the provisions of this section, each agency shall promulgate regulations . . . establishing procedures and guidelines for determining when such fees should be waived or reduced.'' Accordingly, HUD is properly exercising its statutorily granted discretion in establishing that it will consider additional factors in deciding whether to grant requests for a fee waiver or reduction. HUD therefore declines to remove § 15.106(k)(5) from the final rule.

Comment: Applying ''foreseeable harm'' standard for withholding. A commenter stated that HUD should adopt a policy of applying a presumption of openness in processing requests and of only withholding information if it reasonably foresees that disclosure would harm an interest protected by one of the statutory exemptions. According to the commenter, applying this ''foreseeable harm'' standard would help to ensure that HUD does not improperly withhold information. The commenter recommends that HUD revise § 15.107 to add that ''HUD will conduct a foreseeable harm analysis, which clearly identifies the harm that would occur with disclosure.''

Response: HUD withholds documents according to the nine FOIA statutory exemptions that protect various records from disclosure (*see* 5 U.S.C. 552(b)), in conjunction with existing case law and publicly available guidance issued by the Department of Justice. When the request is one that appropriately raises questions of foreseeable harm, HUD staff analyzes the request in light of this standard. Not all requests require this level of review. Accordingly, HUD declines to amend the regulation to incorporate a standard that is not currently reflected in the FOIA.

Comment: Technical amendment to source reference. A commenter recommended that § 15.107(a) be updated to refer to the most current Executive order regarding classified information, which is Executive Order 13526, issued December 29, 2009.

Response: HUD agrees with the commenter and updates this reference in the final rule.

Comment: Avoiding frivolous claims of confidential business information. A commenter suggested that HUD require that submitters of confidential business information use good faith efforts to designate any information that such submitters consider exempt from disclosure under FOIA Exemption 4, and that HUD indicate in this final rule what constitutes a ''good faith effort.'' Specifically, the commenter suggested editing § 15.108(b) to read: ''A blanket designation on each page of a submission that all information contained on the page is protected from disclosure under Exemption 4 presumptively will not be considered a good faith effort.''

Response: Section 15.108(b) of the rule already requires submitters of business information to ''use good faith efforts to designate . . . any portion of its submission that it considers to be protected from disclosure under Exemption 4.'' Furthermore, the commenter's suggested language could create undue processing delays by creating the presumption that entire pages marked as ''business information'' are not marked as such in good faith. In practice, the determination of what constitutes a good faith effort does not hinge on the number of submitted pages entirely marked as ''business information.'' HUD therefore declines to amend this provision.

Comment: Decreased notifications to submitters of ''business information.'' The commenter also suggested that in the interest of avoiding undue delays, HUD establish that it is unnecessary to notify submitters of business information if HUD determines that the claim of confidential business information is obviously frivolous. The commenter also recommended that HUD provide specific time limits, generally 5 working days, for submitters to object to the release of submitted information and this proposed change be incorporated in § 15.108(e).

Response: HUD's current policy regarding the obligation to notify submitters of business information is to provide all of the basic procedural protections that HUD is required to give submitters under Executive Order 12600. It currently is already HUD's practice to grant submitters a reasonable number of days to object to the release of submitted information, as is required by Executive Order 12600, and to require that such objections be justified. HUD therefore declines to amend this provision in the final rule.

Comment: Copies of the original request and adverse determination. A commenter stated that requiring requesters to provide a copy of their original request is unnecessary and unfair because original requests might be difficult to locate after years pass between the time of submission and the appeal. The commenter added that HUD should remove this requirement, as well as the requirement for a copy of the adverse determination, from the proposed rule because many individuals do not have access to a scanner or a photocopier. The commenter suggested that HUD instead ''encourage'' appellants to provide these two copies.

Response: Because HUD often processes multiple requests from the same requester, provision of a copy of the original request and of the original adverse determination helps HUD's reviewing staff to ensure that they issue accurate responses to the original concern or request. Requesting the submission of these copies with an appeal does not pose an unnecessary and unfair burden upon requesters. HUD believes that most requesters have several tools available to make photocopies of important documents, with no exceptional inconvenience to them. In exceptional circumstances, however, requesters might be able to obtain a scanned or printed copy of their original request by contacting the HUD FOIA office handling the request. HUD, therefore, declines to amend § 15.110 of the proposed rule as recommended.

Comment: Providing a longer time period to submit appeals. A commenter suggested that HUD provide requesters with a minimum of 60 days to submit their administrative appeals, instead of the 30 days provided under the rule. The commenter added that this would provide requesters adequate time to gather the necessary information and to formulate any arguments they wish to make in the appeal.

Response: The FOIA provides agencies discretion in setting forth deadlines by which requesters must file their administrative appeals of adverse determinations. HUD's current policy of allowing a requester 30 days to submit an appeal is intended to ensure that FOIA requests and disputes are resolved as promptly as possible. Because an extension of this filing period would defeat this policy goal, HUD declines to amend this provision to, instead, grant requesters 60 days to file appeals to

adverse determinations as recommended.

Comment: Electronic process for appeal submissions. A commenter recommended that HUD provide requesters the option to submit their administrative appeals by email or through the HUD Web site, as opposed to the current process, which requires the submission of appeals ''in writing to the address specified in HUD's notice responding to a FOIA request.''

Response: HUD does not believe that § 15.110 of the proposed rule (redesignated as § 15.109 in this final rule) precludes the submission of an appeal electronically. Nevertheless, HUD has clarified that appeals may be submitted electronically by stating, ''If the letter of appeal is *transmitted electronically* or by a means other than the U.S. Postal Service, it must be received in the appropriate office by the close of business on the 30th calendar day after the date of HUD's letter of determination.'' HUD agrees with the commenter, however, that the public should have the option of submitting their appeals electronically. As a result, HUD has recently expanded its FOIA management system (FMS2), to accommodate the receipt of FOIA appeals electronically. HUD's FOIA management system includes a public access link that allows members of the public to submit FOIA requests electronically and track the status of their requests. HUD agrees that extending these capabilities to the submission of appeals will expedite the review of appeals and ensure that the public is better informed regarding the status of their appeals.

Comment: Notifying requesters of dispute resolution services available for appeal determinations. A commenter stated that HUD should adopt a policy of notifying requesters of dispute resolution services in appeal determination letters. The commenter added that HUD should revise the language at § 15.111(a)(2)(ii) of the proposed rule to add: ''HUD will provide the requester with the name and contact information of the Office of Government Information Services, which offers mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation.''

Response: HUD has considered the commenter's suggestion and agrees to provide requesters notification of dispute resolution services in the appeal determination letters. In addition, HUD will post the contact information for the Office of Government Information Services on its FOIA Web site. See § 15.110(a)(2)(iii).

IV. Findings and Certifications

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select the regulatory approach that maximizes net benefits. Because this final rule incorporates changes enacted by the OPEN Government Act of 2007 and otherwise updates and streamlines HUD's current FOIA regulation, the rule was determined to not be a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and therefore was not reviewed by the Office of Management and Budget.

Environmental Impact

This final rule is categorically excluded from environmental review under the National Environmental Policy Act (42 U.S.C. 4321). The revision of FOIA-related provisions of 24 CFR part 15 falls within the exclusion provided by 24 CFR 50.19(c)(1) in that it does not direct, provide for assistance or loan and mortgage insurance for or otherwise govern or regulate real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This final rule establishes the process by which HUD will respond to requests for information under the FOIA. Costs assessed by HUD for search, review, and duplication required to process the information requested by a requester are limited by the FOIA to direct costs and are not economically significant. As a result, the final rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and on the private sector. This final rule does not impose any Federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

List of Subjects in 24 CFR Part 15

Classified information, Courts, Freedom of information, Government employees, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HUD amends 24 CFR part 15 as follows:

PART 15—PUBLIC ACCESS TO HUD RECORDS UNDER THE FREEDOM OF INFORMATION ACT AND TESTIMONY AND PRODUCTION OF INFORMATION BY HUD EMPLOYEES

Subpart A—General Provisions

■ 1. The authority for 24 CFR part 15 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 5 U.S.C. 552.

■ 2. Revise subpart A to read as follows:

Subpart A—General Provisions

Sec.
15.1 General provisions.
15.2 Definitions.

§ 15.1 General provisions.

(a) *Scope.* Requests for material from HUD will be processed as set forth in this part. The Federal Housing Administration and the Government National Mortgage Association are components of HUD and are also covered by this part.

(b) *Subpart B.* Subpart B of this part contains the rules that HUD follows in processing requests for records under the Freedom of Information Act (FOIA) (5 U.S.C. 552). These rules should be read together with the FOIA, which provides additional information about access to records maintained by HUD.

Information routinely provided to the public as part of a regular Department activity may be provided to the public without following this subpart.

(c) *Subpart C.* Subpart C of this part describes the procedures to be followed and standards to be applied in processing demands for the production of material or provision of testimony in legal proceedings among private litigants.

(d) *Subpart D.* Subpart D of this part describes the procedures to be followed and standards to be applied in processing demands for the production of material or provision of testimony in legal proceedings in which the United States is a party.

(e) *Inspector General.* Subparts B and C of this part do not apply to the Office of Inspector General. The procedures that apply to the Office of Inspector General are described in parts 2002 and 2004 of this title.

§ 15.2 Definitions.

(a) The following definitions apply to this part.

Agency record means any documentary material that is either created or obtained by an agency in the transaction of agency business and is under agency control. ''Agency record'' does not include records that are not already in existence and which would have to be created specifically to meet a request.

Business information means commercial or financial information provided to HUD by a submitter that arguably is protected from disclosure under Exemption 4 (42 U.S.C. 552(b)(4)) of the FOIA.

FOIA means the Freedom of Information Act (5 U.S.C. 552).

HUD means the Department of Housing and Urban Development.

Review means the examination of a record located in response to a request in order to determine whether any portion of it is exempt from disclosure. Review time includes processing any record for disclosure (for example, doing all that is necessary to redact it and prepare it for disclosure). Review costs are recoverable even if a record ultimately is not disclosed. Review time includes time spent considering any formal objection to disclosure, made by a business submitter under § 15.108, but does not include time spent resolving general legal or policy issues regarding the application of exemptions.

Search means the process of looking for and retrieving records or information responsive to a request. It includes page-by-page or line-by-line identification of information within records and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format.

Secretary means the Secretary of Housing and Urban Development.

Submitter means any person or entity that provides business information, directly or indirectly, to HUD. The term includes, but is not limited to, corporations, State governments, and foreign governments.

(b) The following definitions apply to subparts C and D of this part.

Appropriate Associate General Counsel means the Associate General Counsel for Litigation or the Associate General Counsel for HUD Headquarters employees in those programs for which the Associate General Counsel provides legal advice.

Appropriate Regional Counsel means the Regional Counsel for the regional office having delegated authority over the project or activity with respect to which the information is sought. For assistance in identifying the Appropriate Regional Counsel, see appendix A to this part.

Authorized Approving Official means the Secretary, General Counsel, Appropriate Associate General Counsel, or Appropriate Regional Counsel.

Demand means a subpoena, order, or other demand of a court or other authority that is issued in a legal proceeding and any accompanying submissions.

Employee of the Department means a current or former officer or employee of the United States appointed by or subject to the supervision of the Secretary, but does not include an officer or employee covered by part 2004 of this title.

Good cause means necessary to prevent a miscarriage of justice or to promote a significant interest of the Department.

Legal proceeding includes any proceeding before a court of law or other authority; *e.g.,* an administrative board or commission, a hearing officer, an arbitrator, or other body conducting a quasi-judicial or legislative proceeding.

Legal proceeding among private litigants means any legal proceeding in which the United States is not a party.

Legal proceeding in which the United States is a party means any legal proceeding including as a named party the United States, the Department of Housing and Urban Development, any other Federal executive or administrative agency or department, or any official thereof in his official capacity.

Material means either documents or information contained in, or relating to contents of, the files of the Department, or documents or information acquired by any person, while such person was an employee of the Department, as a part of the performance of his or her official duties or because of his or her official status.

Production means to produce material by any means other than through the provision of oral testimony.

Testimony means any oral or written statements made in litigation under oath or penalty of perjury.

United States means the Federal Government of the United States (including the Department), the Secretary, and any employees of the Department in their official capacities.

■ 3. Revise subpart B to read as follows:

Subpart B. Procedures for Disclosure of Records Under the FOIA

Sec.

§ 15.101 Proactive disclosures of department records.

(a) *In General.* Records that are required to be made available for public inspection and copying are accessible on the Department's Web site at *http://www.hud.gov/FOIA.* Published agency records, whether or not they are available for purchase, are made available for examination. Each HUD office (headquarters and field) has a FOIA Public Liaison that can assist individuals in locating records. A list of the Department's FOIA Public Liaisons is available at *http://www.hud.gov/FOIA.*

(b) *Electronic FOIA reading room.* As required by 5 U.S.C. 552(a)(2), HUD makes records created on or after November 1, 1996, available through its electronic FOIA Reading Room, located on HUD's FOIA Web site at *http://www.hud.gov/FOIA.* These records include:

(1) Final opinions and orders.

(2) Public access to high-value, machine readable datasets via http://www/data/gov.

(3) Statements of policy and interpretation, including:

(i) HUD's Client and Information Policy Systems (HUDCLIPS);

(ii) Housing policy;

(iii) Public and Indian Housing policy and regulations;

(iv) Public and Indian Housing policy and guidance (PHA Plans); and

(v) Community Planning and Development policy and guidance.

(4) Administrative staff manuals.

(5) HUD's online library.

(6) Fair housing information.

(c) *Frequently requested materials.* HUD also makes frequently requested materials available on its FOIA Web site at *http://www.hud.gov/FOIA.* These frequently requested materials include information related to:

(1) Highest-scoring funding grant applications.

(2) Purchase charge cardholders.

(3) FHA refunds.

(4) FHA-approved lenders.

(5) Homes for sale.

(6) How to buy a HUD home.

(7) How to apply for public housing and Section 8 housing.

(8) Housing for the elderly.

(9) Housing for individuals with disabilities.

(10) HUD contracting home page.

(11) FHA mortgage insurance programs.

(12) HUD handbooks.

(13) HUD programs.

(14) HUD telephone directory.

(15) HUD homes listing.

(16) HUD's organization.

(17) Multifamily housing data.

(18) Public housing authority contact information.

(19) Weekly listing of multifamily properties for sale.

(20) Catalog of Federal Domestic Assistance (CFDA) materials.

(21) Grants.

(22) FOIA request logs.

§ 15.102 Requirements for making requests for records.

(a) *In general.* Any request for HUD records must be made in writing and submitted to the FOIA Public Liaison in the HUD field office where the records are located or to the Office of the Executive Secretariat in HUD Headquarters if the request is for records located in HUD Headquarters.

(b) *HUD field office records.* Requests for records located in a HUD field office may be submitted by mail (including courier or delivery service), email, or facsimile to the FOIA Public Liaison at the field office.

(c) *HUD headquarters records.* Requests for records located in HUD Headquarters may be submitted via an electronic request form on HUD's FOIA Web site at *http://www.hud.gov/FOIA.* Requests can also be submitted in person or by mail (including courier or delivery service), email, or facsimile to the Office of the Executive Secretariat in HUD Headquarters.

(d) *Form of requests.* FOIA requests should:

(1) Be in writing and clearly identifiable as a FOIA request. To facilitate identification, the requester should place the phrase ''FOIA Request'' on the front of the envelope or on the cover sheet or other transmittal document used when submitting the request in person or by mail, email, facsimile, or electronic request form;

(2) Include, whenever possible, detailed and specific information about each record sought, such as the date, title or name, author, recipient, and subject matter of the record. The more specific the FOIA request for records, the more likely HUD officials will be able to locate the records requested. Requests for categories of information should be for specific and well-defined categories. Insufficient descriptions may lead HUD officials to contact the requester to seek additional information for their record search;

(3) Indicate the form or format in which the requester would like the record made available, if the requester has a preference;

(4) Specify the fee amount the requester is willing to pay. In general, HUD provides records at no cost up to $25. Requesters are required to agree to pay for any costs that exceed $25. Requesters may also request a dollar amount above which HUD should consult with them before they agree to pay the fee. If a requester seeks a fee waiver or reduction, the requester should include this request with the FOIA disclosure request and should describe, consistent with § 15.106(k), how the disclosure of the requested information is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester;

(5) Indicate the fee category that the requester believes applies to each of his or her requests (fee categories are defined in § 15.106(b));

(6) Include verification information of the requester's identity, if the requester requests agency records pertaining to the requester, a minor, or an individual who is legally incompetent. Information about what constitutes acceptable verification information can be found in HUD's Privacy Act regulations in 24 CFR part 16;

(7) Contain signed authorization from the other person, if the requester makes a request on another person's behalf for information about that person. If necessary, HUD will inform the requester of the authorization needed from the other person and give the requester an opportunity to provide such authorization. Requests for information about another person should be accompanied by either written, notarized authorization or proof that the individual is deceased (for example, a copy of a death certificate or an obituary), or the request will be deemed insufficient; and

(8) Contain a detailed explanation of the basis for the request, if the requester makes a request for expedited processing as provided by § 15.104(c). The requester should also include a statement certifying the truth of the circumstances alleged or other evidence, acceptable to HUD, of the requester's compelling need.

§ 15.103 Timing of responses to requests.

(a) *In general.* HUD will generally respond to a FOIA request within 20 working days, depending on the size of the request. The 20-day period will begin on the day the request is received by the appropriate component of HUD, but in any event not later than 10 working days after the request is received by any component of HUD designated to receive FOIA requests.

(b) *Tolling the 20-day time period.* Under the OPEN Government Act of 2007, HUD may toll the 20-day period:

(1) One time to make a reasonable request for additional information from the requester; or

(2) As many times as necessary to clarify issues regarding fee assessment with the requester. The agency's receipt of the requester's response to the agency's request for information or resolution of all fee assessment issues ends the tolling period.

(c) *Extension of time periods for processing a request.* In unusual circumstances, as defined in this paragraph, HUD may extend the time period for processing a FOIA request. In such circumstances, HUD will provide the requester with written notice setting forth the unusual circumstances for the extension and the date on which a determination is expected to be dispatched. This date will not exceed 10 working days beyond the general time limit established in paragraph (a) of this section. If processing a request would require more than 10 working days beyond the general time limit established in paragraph (a) of this section, HUD will offer the requester an opportunity to limit the scope of the request so that HUD may process it within the extra 10-day working period or arrange an alternative time period within which the FOIA request will be processed. For purposes of this section, unusual circumstances include:

(1) The need to search for and collect records not located in the office processing the request;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records; or

(3) The need to consult with another agency or two or more HUD components having a substantial interest in the determination of the FOIA request.

(d) *Aggregating multiple requests.* (1) HUD may aggregate multiple requests in cases where unusual circumstances exist and HUD determines that:

(i) Certain requests from the same requester or from a group of requesters acting in concert actually constitute a single request; and

(ii) The requests involve clearly related matters.

(2) Aggregation of requests for this purpose will be conducted independent of aggregation of requests for fee purposes under § 15.106(h).

§ 15.104 Procedures for processing FOIA requests.

(a) *In general.* HUD will ordinarily respond to FOIA requests according to their order of receipt.

(b) *Tracking number.* FOIA requests will be logged in the order that they are received and be assigned a tracking number. A requester should use the tracking number to identify his or her request when contacting FOIA office for any reason.

(c) *Expedited processing.* (1) Requests and appeals will be taken out of order and given expedited treatment whenever it is determined that they involve:

(i) Circumstances in which the lack of expedited treatment could reasonably be expected to pose an imminent threat to the life or physical safety of an individual;

(ii) An urgency to inform the public about an actual or alleged Federal Government activity, if made by a person primarily engaged in disseminating information; or

(iii) The loss of substantial due process rights.

(2) A request for expedited processing may be made at the time of the initial request for records or at any later time. For a prompt determination, a request for expedited processing should be received by the proper office designated to receive FOIA requests as provided in § 15.102.

(3) A requester who seeks expedited processing should submit a statement, certified to be true and correct to the best of that person's knowledge and belief, explaining in detail the basis for requesting expedited processing. For example, a requester who makes a request under paragraph (c)(1)(ii) of this section, if not a full-time member of the news media, should establish that he or she is a person primarily engaged in disseminating information, though it need not be his or her sole occupation. A requester making a request under paragraph (c)(1)(ii) of this section also should establish a particular urgency to inform the public about the government activity involved in the request, beyond the public's right to know about government activity generally. The formality of certification may be waived as a matter of administrative discretion.

(4) HUD will make a determination within 10 calendar days of receipt by the appropriate component of HUD, as provided in § 15.103, whether to grant or deny a request for expedited processing and notify the requester of HUD's determination. FOIA requests accepted for expedited processing will be processed as soon as practicable and on a priority basis.

(d) *Multitrack processing.* (1) For requests that do not qualify for expedited processing, HUD may use two or more processing tracks by distinguishing between simple and complex FOIA requests based on the following: The time and work necessary to process the FOIA request and the volume of agency records responsive to the FOIA request.

(2) When HUD uses multitrack processing, it may provide requesters in its slower track an opportunity to limit the scope of their requests in order to qualify for faster processing within the specified limits of HUD's faster track. When HUD chooses to provide this option, HUD will contact the requester by telephone, letter, or email, whichever is more efficient in each case.

§ 15.105 Responses to requests.

(a) *Acknowledgements of requests.* The FOIA office in the Office of the Executive Secretariat in HUD Headquarters and FOIA Public Liaison in each HUD field office will ordinarily send an acknowledgement letter to the requester that will confirm receipt of the request by the appropriate HUD office and provide an assigned tracking number, as provided by § 15.104(b), for further reference.

(b) *Consultations, coordination, and referrals.* When HUD receives a request for a record in its possession, it shall determine whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA or whether it should be disclosed as a matter of administrative discretion. If HUD determines that it is best able to determine whether the record is exempt from disclosure, then it shall do so. If HUD determines that it is not best able to make that determination, then it shall either:

(1) Respond to the request regarding that record, after consulting with the agency best able to determine whether to disclose it and with any other agency that has a substantial interest in it; or

(2) Refer the responsibility for responding to the request regarding that record to the agency that originated the record, but only if that agency is subject to the FOIA. Ordinarily, the agency with which the record originated will be presumed to be best able to determine whether to disclose it.

(c) *Fee estimates.* HUD will notify the requester if HUD's estimate of the fee is more than the requester has agreed to pay. Consistent with § 15.106(e), the requester shall have 15 working days to agree to pay the higher fee.

(d) *Forms of response.* (1) Granting requests in whole or in part. Once HUD makes a determination to grant a request in whole or in part, it will notify the requester in writing. HUD will make a record available in the form or format requested, if the record is readily reproducible in that format. HUD will inform the requester in the notice of any fee charged under § 15.106 and disclose records to the requester promptly upon payment of any applicable fee. Records disclosed in part will be marked or annotated to show the amount of information deleted and the exemption(s) under which each deletion is made, unless doing so would harm an interest protected by an applicable FOIA exemption. The location of the information deleted and the exemption(s) under which the deletion is made will be indicated directly on the record itself, if technically feasible.

(2) Adverse determination of requests. If a determination is made to deny a request in any respect, HUD shall notify the requester of that determination in writing. Adverse determinations, or denials of requests, include: A determination to withhold any requested record, in whole or in part; a determination that a requested record does not exist, cannot be located, or has not been retained; a determination that a record is not readily reproducible in the form or format sought by the requester; a determination that what has been requested is not a record subject to the FOIA; a determination on any disputed fee matter, including a denial of a request for a fee waiver or reduction; and a denial of a request for expedited treatment. The denial letter shall be signed by the Director of the Office of the Executive Secretariat, or a

designee of the Director, in HUD Headquarters or the FOIA Public Liaison for the HUD field office where the adverse determination was made, and shall include:

(i) The name and title or position of the person responsible for the denial;

(ii) A brief statement of the reason(s) for the denial, including any FOIA exemption applied by HUD in denying the request;

(iii) An estimate of the volume of records or information withheld, when appropriate, in number of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through deletions on records disclosed in part, or if providing an estimate would harm an interest protected by an applicable exemption; and

(iv) A statement that the denial may be appealed as provided by § 15.109 and a description of the requirements for appeal.

§ 15.106 Fees.

(a) *In general.* HUD will charge for processing requests under the FOIA in accordance with paragraph (c) of this section, except where fees are limited under paragraph (d) of this section or where a waiver or reduction of fees is granted under paragraph (k) of this section. HUD shall collect all applicable fees before sending copies of requested records to a requester. In order to resolve any fee issues that arise under this section, HUD may contact a requester for additional information. Requesters shall pay fees by check or money order made payable to the United States Treasury.

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

Commercial use means a request from or on behalf of a person who seeks information for a use or purpose that furthers his or her commercial, trade, or profit interests, which can include furthering those interests through litigation. HUD shall determine, whenever reasonably possible, the use to which a requester will put the requested records. When it appears that the requester will put the records to a commercial use, either because of the nature of the request itself or because HUD has reasonable cause to doubt a requester's stated use, HUD shall provide the requester a reasonable opportunity to submit further clarification.

Direct costs means those expenses that HUD actually incurs in searching for and duplicating and, in the case of commercial use requests, reviewing records to respond to a FOIA request. Direct costs include, for example, the salary of the employee performing the work and the cost of operating computers and other electronic equipment, such as for mainframe computer run time. Not included in direct costs are overhead expenses such as the costs of space and heating or lighting a facility.

Duplication means the process of making a copy of a document necessary to respond to a FOIA request. Such copies can take the form of paper copy, audiovisual materials, or machine readable documentation (*e.g.,* diskette), among others. HUD shall honor a requester's specified preference of form or format of disclosure if the record is readily reproducible with reasonable efforts in the requested form or format by the office responding to the request.

Educational institution means:

(i)(A) A preschool;

(B) A public or private elementary or secondary school;

(C) An institution of graduate higher education;

(D) An institution of undergraduate higher education;

(E) An institution of professional education; or

(F) An institution of vocational education, that primarily (or solely) operates a program or programs of scholarly research.

(ii) To be in this category, a requester should show that the request is authorized by, and is made under the auspices of, a qualifying institution and that the records are not sought for a commercial use but are sought to further scholarly research. Records requested for the intention of fulfilling credit requirements are not considered to be sought for a scholarly purpose.

Other requester means any requester that does not fall within the categories of requesters described in this section.

Noncommercial scientific institution means an institution that is not operated on a ''commercial'' basis, as defined in this section, and that is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry. To be in this category, a requester should show that the request is authorized by, and is made under the auspices of, a qualifying institution and that the records are not sought for a commercial use but are sought to further scientific research.

Representative of the news media, or *news media requester,* means any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term *news* means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations broadcasting to the public at large and publishers of periodicals that disseminate news and make their products available to the general public through a variety of means. For freelance journalists to be regarded as working for a news media entity, they should demonstrate a solid basis for expecting publication through a news media entity. A publication contract would be the clearest proof, but HUD will also look to the past publication record of a requester in making this determination. To be in this category a requester should not be seeking the requested records for a commercial use. However, a request for records supporting the news dissemination function of the requester shall not be considered to be for a commercial use.

(c) *Fees*—(1) *Schedule.* In responding to FOIA requests, HUD will use the fee schedule set out in the following table, unless a waiver or reduction of fees has been granted under paragraph (k) of this section.

FOIA FEE SCHEDULE

Activity	Rate	Commercial use requester	News media, educational institution, or noncommercial scientific institution requester	Other requester
(i) Professional search	$13 per quarter hour	Applies	Does not apply	Applies. No charge for first 2 hours of cumulative search time.
(ii) Professional review	$13 per quarter hour	Applies	Does not apply	Does not apply.

FOIA FEE SCHEDULE—Continued

Activity	Rate	Commercial use requester	News media, educational institution, or noncommercial scientific institution requester	Other requester
(iii) Clerical search	$6 per quarter hour	Applies	Does not apply	Applies. No charge for first 2 hours of cumulative search time.
(iv) Clerical review	$6 per quarter hour	Applies	Does not apply	Does not apply.
(v) Programming services required.	Direct costs associated with search.	Applies	Does not apply	Applies.
(vi) Duplication costs	$0.10 per page	Applies	Applies. No charge for first 100 pages.	Applies. No charge for first 100 pages.
(vii) Duplication costs—tape, CD ROM or diskette.	Actual cost	Applies	Applies	Applies.

(2) *Search.* (i) Search fees will be charged for all requests other than requests made by educational institutions, noncommercial scientific institutions, or representatives of the news media, subject to the limitations of paragraph (d) of this section. HUD may charge for time spent searching even if HUD does not locate any responsive record or if HUD withholds the record(s) located as entirely exempt from disclosure.

(ii) For each hour spent by personnel searching for requested records, including electronic searches that do not require new programming, the fees will be $13 per quarter hour for professional personnel and $6 per quarter hour for clerical personnel.

(iii) Requesters will be charged the direct costs associated with conducting any search that requires the creation of a new program to locate the requested records.

(iv) For requests requiring the retrieval of records from any Federal records center, certain additional costs may be incurred in accordance with the Transactional Billing Rate Schedule established by the National Archives and Records Administration.

(3) *Duplication.* Duplication fees will be charged to all requesters, subject to the limitations of paragraph (d) of this section. For a paper photocopy of a record (no more than one copy of which need be supplied), the fee will be $0.10 per page. For copies in digital format, HUD will charge the direct costs, including operator time, of producing the copy. Where paper documents must be scanned in order to comply with a requester's preference to receive the records in an electronic format, the requester shall pay the direct costs associated with scanning those materials. For other forms of duplication, HUD will charge the direct costs.

(4) *Review.* Review fees will be charged to requesters who make a commercial use request. Review fees will be charged only for the initial record review (the review done where HUD determines whether an exemption applies to a particular record or record portion, at the initial request level). No charge will be made for review at the administrative appeal level for an exemption already applied. However, records or portions of records withheld under an exemption that is subsequently determined not to apply may be reviewed again to determine whether any other exemption not previously considered applies. The cost of that review is chargeable where it is made necessary by such a change of circumstances. Fees for the review time will be $13 per quarter hour for professional personnel and $6 per quarter hour for clerical personnel.

(d) *Restrictions on charging fees.* (1) No search fee will be charged for requests by educational institutions, noncommercial scientific institutions, or representatives of the news media. In addition, when HUD fails to comply with the applicable time limits in which to respond to a request and no unusual or exceptional circumstance, as those terms are defined by the FOIA, apply to the processing of the request, HUD will not charge search fees, or in the instances of requests from educational institutions, noncommercial scientific institutions, or representatives of the news media, as defined by paragraph (b) of this section, HUD will not charge duplication fees.

(2) Search and review fees will be charged in quarter-hour increments. HUD will round up a quarter hour when professional and clerical search and review time exceeds a quarter-hour increment.

(3) Except for requesters seeking records for a commercial use, HUD will provide without charge:

(i) The first 100 pages of duplication (or the cost equivalent); and

(ii) The first 2 hours of search (or the cost equivalent).

(4) No fee will be charged whenever a total fee calculated under paragraph (c) of this section is less than HUD's cost to process the payment. Currently, whenever a total fee calculated is $25 or less, no fee will be charged.

(e) *Notice of anticipated fees in excess of $25.* When HUD determines or estimates that the fees to be charged under this section will amount to more than $25, HUD will notify the requester of the actual or estimated amount of the fees, unless the requester has indicated a willingness to pay fees as high as the amount anticipated. If only a portion of the fee can be readily estimated, HUD shall advise the requester that the estimated fee may be only a portion of the total fee. In cases in which a requester has been notified that actual or estimated fees amount to more than $25, the request will be held in abeyance for 15 working days. Further work will not be done on that request until the requester has either made a firm commitment to pay the anticipated total fee, or has made payment in advance if the total fee exceeds $250. Any such agreement should be memorialized by the requester in writing, should indicate a given dollar amount, and should be received by HUD within the time period specified by HUD in its notice to the requester. If the requester does not provide a firm commitment to pay the anticipated fee within the time period specified by HUD, the request will be closed. A notice under this paragraph will offer the requester an opportunity to discuss the matter of fees with HUD personnel in order to reformulate the request to meet the requester's needs at a lower cost. HUD is not required to accept payments in installments.

(f) *Charges for other services.* Although not required to provide special services, if HUD chooses to do so as a matter of administrative discretion, HUD will charge the direct costs of providing these services. Examples of such services include certifying that records are true copies, providing multiple copies of the same document, or sending documents by means other than ordinary mail.

(g) *Charging interest.* HUD may charge interest on any unpaid bill starting on the 31st day following the date of billing the requester. Interest charges will be assessed at the rate provided in 31 U.S.C. 3717 and will accrue from the date of the billing until payment is received by HUD. HUD will follow the provisions of the Debt Collection Act of 1982 (Pub. L. 97–365, 96 Stat. 1749), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset.

(h) *Aggregating requests.* If HUD reasonably believes that a requester or a group of requesters acting together is attempting to divide a request into a series of requests for the purpose of avoiding fees, HUD may aggregate those requests and charge accordingly. HUD may presume that multiple requests of this type made within a 30-day period have been made in order to avoid fees. Where requests are separated by a longer period, HUD will aggregate them only where there is a reasonable basis for determining that aggregation is warranted under all the circumstances involved. Multiple requests involving unrelated matters will not be aggregated. Aggregation of requests for fee purposes under this paragraph will be conducted independent of aggregation of requests under § 15.103(d).

(i) *Advance payments.* (1) For requests other than those described in paragraphs (i)(2) and (3) of this section, HUD will not require the requester to make an advance payment before work is begun or continued on a request. Payment owed for work already completed, such as prepayment before copies are sent to a requester, is not an advance payment.

(2) If HUD determines or estimates that a total fee to be charged under this section will be more than $250, it may require the requester to make an advance payment of an amount up to the amount of the entire anticipated fee before beginning to process the request, except where it receives a satisfactory assurance of full payment from a requester who has a history of prompt payment.

(3) If a requester has previously failed to pay a properly charged FOIA fee to HUD within 30 days of the date of billing, before HUD begins to process a new request or continues to process a pending request from that requester, HUD will require the requester to pay the full amount due, plus any applicable interest, and to make an advance payment of the full amount of any anticipated fee. If HUD has a reasonable basis to believe that a requester has misrepresented his or her identity in order to avoid paying outstanding fees, HUD may require that the requester provide proof of identity.

(4) When HUD requires advance payment, the request will be held in abeyance for 15 working days to allow the requester an opportunity to make payment in advance and/or modify the scope of the request. If the requester does not pay the advance payment or modify the scope of the request within the allotted time frame, the request will be closed.

(j) *Other statutes specifically providing for fees.* The fee schedule in this section does not apply to fees charged under any statute that specifically requires an agency to set and collect fees for particular types of records. Where records responsive to requests are maintained for distribution by agencies operating such statutorily based fee schedule programs, HUD will inform requesters of the contact information for that source.

(k) *Requirements for waiver or reduction of fees.* (1) Records responsive to a request will be furnished without charge or at a charge reduced below that established under paragraph (c) of this section if HUD determines, based on all available information, that the requester has demonstrated the following:

(i) Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government; and

(ii) Disclosure of the information is not primarily in the commercial interest of the requester.

(2) To determine whether the first fee waiver requirement is met, HUD will consider the following factors:

(i) The subject of the requested records should concern identifiable operations or activities of the Federal Government, with a connection that is direct and clear, not remote or attenuated.

(ii) The disclosable portions of the requested records should be meaningfully informative about government operations or activities and ''likely to contribute'' to an increased public understanding of those operations or activities. The disclosure of information that already is in the public domain, in either a duplicative or a substantially identical form, would not be as likely to contribute to such increased understanding, where nothing new would be added to the public's understanding.

(iii) The disclosure should contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area and ability and intention to effectively convey information to the public will be considered. It will be presumed that a representative of the news media will satisfy this consideration.

(iv) The public's understanding of the subject in question, as compared to the level of public understanding existing prior to the disclosure, should be enhanced by the disclosure to a significant extent. However, HUD will not make value judgments about whether information at issue is ''important'' enough to be made public.

(3) To determine whether the second fee waiver requirement is met, HUD will consider the following factors:

(i) HUD will identify any commercial interest of the requester as defined in paragraph (b) of this section, or of any person on whose behalf the requester may be acting, that would be furthered by the requested disclosure. Requesters shall be given an opportunity in the administrative process to provide explanatory information regarding this consideration.

(ii) A fee waiver or reduction is justified where the public interest standard is satisfied and that public interest is greater than that of any identified commercial interest in disclosure. HUD ordinarily will presume that where a news media requester has satisfied the public interest standard, the public interest will be the interest primarily served by disclosure to that requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return will not be presumed to primarily serve the public interest.

(4) Where only some of the records to be released satisfy the requirements for a waiver of fees, a waiver will be granted for those records.

(5) Requests for the waiver or reduction of fees should address the factors listed in paragraphs (k)(2) and (3) of this section, insofar as they apply to each request. In deciding to grant waivers or reductions of fees, HUD will exercise its discretion to consider the cost effectiveness of its investment of administrative resources.

§ 15.107 Documents generally protected from disclosure.

The FOIA contains nine exemptions (5 U.S.C. 552(b)) that authorize agencies to withhold various records from disclosure. With regard to certain types of records, HUD generally applies the exemptions as follows:

(a) *Classified documents.* Exemption 1 (5 U.S.C. 552(b)(1)) protects classified national defense and foreign relations information. HUD seldom relies on this exception to withhold documents. However, where applicable, HUD will refer a request for records classified under Executive Order 13526 and the pertinent records to the originating agency for processing. HUD may refuse to confirm or deny the existence of the requested information if the originating agency determines that the fact of the existence of the information itself is classified.

(b) *Internal agency rules and practices.* Exemption 2 (5 U.S.C. 552(b)(2)) protects records relating to internal personnel rules and practices.

(c) *Information prohibited from disclosure by another statute.* Exemption 3 (5 U.S.C. 552(b)(3)) protects information that is prohibited from disclosure by another Federal law. HUD generally will not disclose competitive proposals prior to contract award, competitive proposals that are not set forth or incorporated by reference into the awarded contract, (see 41 U.S.C. 4702), or, during the selection process, any covered selection information regarding such selection, either directly or indirectly (see 42 U.S.C. 3537a).

(d) *Commercial or financial information.* Exemption 4 (5 U.S.C. 552(b)(4)) protects trade secrets and commercial or financial information obtained from a person that is privileged and confidential. HUD will handle this type of information as provided by § 15.108.

(e) *Certain interagency or intra-agency communications.* Exemption 5 (5 U.S.C. 552(b)(5)) protects interagency or intra-agency communications that are protected by legal privileges, such as the attorney-client privilege, attorney work-product privilege, or communications reflecting the agency's deliberative process.

(f) *Personal privacy.* Exemption 6 (5 U.S.C. 552(b)(6)) protects information involving matters of personal privacy. This information may include personnel, medical, and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Names, addresses, telephone numbers, and email addresses of persons residing in public or assisted housing or of borrowers in FHA-insured single family mortgage transactions generally will not be disclosed.

(g) *Law enforcement records.* Exemption 7 (5 U.S.C. 552(b)(7)) protects certain records or information compiled for law enforcement purposes. This exemption protects records where the production could reasonably be expected to interfere with enforcement proceedings; for example, the names of individuals who have filed fair housing complaints. The protection of this exemption also encompasses, but is not limited to, information in law enforcement files that could reasonably be expected to constitute an unwarranted invasion of personal privacy; the names of confidential informants; and techniques and procedures for law enforcement investigations, or guidelines for law enforcement investigations if such disclosure could reasonably be expected to risk circumvention of the law.

(h) *Supervision of financial institutions.* Exemption 8 (5 U.S.C. 552(b)(8)) protects information relating to the supervision of financial institutions. For purposes of Exemption 8, HUD is an ''agency responsible for the regulation and supervision of financial institutions'' for purposes of monitoring fair housing compliance.

(i) *Wells.* Exemption 9 (5 U.S.C. 552(b)(9)) protects geological information on wells.

§ 15.108 Business information.

(a) *In general.* Business information obtained by HUD from a submitter will be disclosed under the FOIA only under this section. In making final confidentiality determinations under this section, HUD relies to a large extent upon the information furnished by the affected business to substantiate its claim of confidentiality. HUD may be unable to verify the accuracy of much of the information submitted by the affected business. HUD will comply with Executive Order 12600 and follow the procedure in this section by giving notice to the affected business and an opportunity for the business to present evidence of its confidentiality claim. If HUD is sued by a requester under the FOIA for nondisclosure of confidential business information, HUD expects the affected business to cooperate to the fullest extent possible in defending such a decision.

(b) *Designation of business information.* A submitter of business information will use good faith efforts to designate, by appropriate markings, either at the time of submission or at a reasonable time thereafter, any portions of its submission that it considers to be protected from disclosure under Exemption 4. These designations will expire 10 years after the date of the submission unless the submitter requests, and provides justification for, a longer designation period.

(c) *Notice to submitters.* HUD will provide a submitter with prompt written notice of a FOIA request or administrative appeal that seeks business information, wherever required under paragraph (d) of this section, in order to give the submitter an opportunity to object to disclosure of any specified portion of that information under paragraph (e) of this section. The notice will either describe the business information requested or include copies of the requested records or portions of records containing the information. When notification of a voluminous number of submitters is required, notification may be made by posting or publishing the notice in a place reasonably likely to accomplish notification.

(d) *Where notice is required.* Notice will be given to a submitter wherever:

(1) The information has been designated in good faith by the submitter as information considered protected from disclosure under Exemption 4; or

(2) HUD has reason to believe that the information may be protected from disclosure under Exemption 4.

(e) *Opportunity to object to disclosure.* HUD will allow a submitter a reasonable time to respond to the notice described in paragraph (c) of this section and will specify that time period within the notice. If a submitter has any objection to disclosure, the submitter should submit a detailed written statement specifying the grounds for withholding any portion of the information under any exemption of the FOIA and, in the case of Exemption 4, the submitter should show why the information is a trade secret or commercial or financial information that is privileged or confidential. HUD generally will not consider conclusory statements that particular information would be useful to competitors or would impair sales, or other similar statements, sufficient to justify confidential treatment. In the event that a submitter fails to respond to the notice within the time specified, the submitter will be considered to have no objection to the disclosure of the information. Information provided by the submitter that is not received until after the disclosure decision has been made will not be considered by HUD. Information provided by a submitter under this paragraph may itself be subject to disclosure under the FOIA.

(f) *Notice of intent to disclose.* HUD will consider a submitter's objections and specific grounds for nondisclosure in deciding whether to disclose business information. Whenever HUD decides to disclose business information over the objection of a submitter, HUD will give the submitter written notice, which will include:

(1) A statement of the reason(s) why each of the submitter's disclosure objections was not sustained;

(2) A description of the business information to be disclosed; and

(3) A specified disclosure date, which shall be a reasonable time subsequent to the notice.

(g) *Exceptions to notice requirements.* The notice requirements of paragraphs (c) and (f) of this section will not apply if:

(1) HUD determines that the information should not be disclosed;

(2) The information lawfully has been published or has been officially made available to the public; or

(3) Disclosure of the information is required by statute (other than the FOIA) or by a regulation issued in accordance with the requirements of Executive Order 12600.

(h) *Notice of a FOIA lawsuit.* Whenever a requester files a lawsuit seeking to compel the disclosure of business information, HUD will promptly notify the submitter.

(i) *Corresponding notice to requesters.* Whenever HUD provides a submitter with notice and an opportunity to object to disclosure under paragraph (f) of this section, HUD will also notify the requester(s). Whenever a submitter files a lawsuit seeking to prevent the disclosure of business information, HUD will notify the requester(s).

§ 15.109 Appeals.

(a) *In general.* A requester may appeal an adverse determination denying a request, in any respect, in writing. The letter of appeal should clearly identify the determination that is being appealed and the assigned tracking number. The appeal letter and envelope should be marked ''Freedom of Information Act Appeal'' for the quickest possible handling. If mailed, the requester's letter of appeal must be postmarked within 30 calendar days of the date of HUD's letter of determination. If the letter of appeal is transmitted electronically or by a means other than the United States Postal Service, it must be received in the appropriate office by the close of business on the 30th calendar day after the date of HUD's letter of determination.

(b) *Time frames*—(1) Expedited processing. HUD will decide an appeal of a denial of a request to expedite processing of a FOIA request within 10 working days of receipt of the appeal.

(2) *All other appeals.* HUD will make a determination on appeals within 20 working days of receipt, unless unusual circumstances require HUD to extend the time for an additional 10 working days.

(3) *Exceptions.* An appeal ordinarily will not be acted upon if the subject of the appeal is simultaneously being litigated in an applicable Federal court.

(c) *Content of appeals.* An appeal letter should include the following:

(1) A copy of the original request;

(2) A copy of the adverse determination;

(3) A statement of facts and legal arguments supporting the appeal; and

(4) Any additional information the appellant wishes to include.

(d) *When appeal is required.* Before seeking a court review of HUD's adverse determination, a requester generally must have exhausted their administrative remedies.

§ 15.110 HUD response to appeals.

(a) *In general.* (1) The appellate official will conduct a de novo review of the entire record and applicable law when making a decision.

(2) The decision on the appeal will be made in writing and will be considered the final action of HUD.

(i) A decision affirming an adverse determination, in whole or in part, will contain a statement of the reason(s) for the affirmation, including any FOIA exemption(s) applied, and will inform the appellant of the FOIA provisions for potential court review of the decision.

(ii) If the adverse determination is modified on appeal, in whole or in part, a written decision will be sent to the appellant and the FOIA request will be reprocessed in accordance with the appeal decision.

(iii) Adverse decisions will include the name and contact information of dispute resolution services that offer mediation services to resolve disputes between FOIA requesters and Federal agencies as a nonexclusive alternative to litigation.

(b) *Appeal of a denial of record request.* Upon appeal of a denial of a record request, the appellate official will issue a decision that either:

(1) Overturns the adverse determination, in whole or in part, and remands the request to the appropriate office. The requester will be notified of the rationale for the determination in writing. The original office will then reprocess the request in accordance with the appeal determination and respond directly to the requester; or

(2) Affirms the adverse determination and declines to provide the requested records to the appellant.

(c) *Appeal of a fee determination.* Upon appeal of a fee determination, the appellate official will issue a decision that either:

(1) Waives the fee or charges the fee that the appellant requested;

(2) Modifies the original fee charged and explains why the modified fee is appropriate; or

(3) Advises the appellant that the original fee charged was appropriate and gives the reason behind this determination.

(d) *Appeal of a denial of expedited processing.* Upon appeal of a denial of an expedited processing request, the appellate official will issue a decision that either:

(1) Overturns the adverse determination and grants the expedited processing request; or

(2) Affirms the decision to deny expedited processing.

Date: August 7, 2015.

Nani A. Coloretti,

Deputy Secretary.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2015–0701]

RIN 1625–AA00

Safety Zone, James River; Newport News, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone on the navigable waters of the James River, in the vicinity of the James River Reserve Fleet, in support of United States Navy explosives training on the M/V SS DEL MONTE. This safety zone will restrict vessel movement in the specified area during the explosives training. This action is necessary to provide for the safety of life and property on the surrounding navigable waters during the United States Navy explosives training.

DATES: This rule is effective and enforced from 8 a.m. on August 17, 2015 until 4 p.m. on August 21, 2015.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2015–0701]. To view documents

mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Barbara Wilk, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone (757) 668–5580, email *HamptonRoadsWaterway@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this temporary final 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 written 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)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule due to the fact that this military training is necessary to train and qualify Navy personnel in the use of explosives. This training is imperative to ensure that Navy personnel located within the Fifth Coast Guard District are properly trained and qualified before conducting military and national security operations for use in securing ports and waterways. Navy policy requires that Navy personnel meet and maintain certain qualification standards before being allowed to carry out certain missions. Failure to conduct this required training at this time will result in a lapse in personnel qualification standards and, consequently, the inability of Navy personnel to carry out important national security functions at any time. The Coast Guard received the information about this event on July 20, 2015; delaying the effective date by first publishing an NPRM would be contrary to the safety zone's intended objectives as well as to the public interest because immediate action is needed to protect persons and vessels against the hazards associated. The Coast Guard will provide advance notification to users of the affected waterway via marine information broadcasts and local notice to mariners. The Coast Guard will provide advance notifications to users of the affected waterway via marine information broadcasts and local notice to mariners.

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**. Due to the need for immediate action, the restriction on vessel traffic is necessary to protect life, property and the environment; therefore, a 30-day notice is impracticable. Delaying the effective date would be contrary to the safety zone's intended objectives of protecting persons and vessels, and enhancing public and maritime safety.

B. Basis and Purpose

The legal basis and authorities for this rule are found in 33 U.S.C. 1231; 33 CFR 1.05–1, 6.04–1, 160.5; Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to propose, establish, and define regulatory safety zones.

The purpose of this safety zone is to protect the participants, patrol vessels, and other vessels transiting navigable waters of the James River, in the vicinity of the James River Reserve Fleet, from hazards associated with military explosives operations. The potential hazards to mariners within the safety zone include shock waves, flying shrapnel, and loud noises.

C. Discussion of the Final Rule

The Captain of the Port of Hampton Roads is establishing a safety zone on specified waters of the James River, in the vicinity of the James River Reserve Fleet, in Newport News, VA. The safety zone will encompass all navigable waters within a 1500 foot radius of the SS DEL MONTE location at position 37°06′11″ N., 076°38′40″ W. (NAD 1983). This safety zone will be established and enforced from 8 a.m. on August 17, 2015 until 4 p.m. on August 21, 2015. Access to the safety zone will be restricted during the specified dates and times. Except for participants and vessels authorized by the Captain of the Port of his Representative, no person or vessel may enter or remain in the regulated area.

The Captain of the Port will give notice of the enforcement of the safety zone by all appropriate means to provide the widest dissemination of notice to the affected segments of the public. This includes publication in the Local Notice to Mariners and Marine Information Broadcasts.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. Although this safety zone restricts vessel traffic through the regulated area, the effect of this rule will not be significant because: (i) This rule will only be enforced for the limited size and duration of the event; and (ii) the Coast Guard will make extensive notification to the maritime community via marine information broadcasts so mariners may adjust their plans accordingly.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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. This rule affects the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in waters of the Eastern Branch of the Elizabeth River during the enforcement period.

This safety zone will not have a significant economic impact on a substantial number of small entities for

the following reasons: (i) The safety zone is of limited size and duration, and (ii) Sector Hampton Roads will issue maritime advisories widely available to users of the James River allowing mariners to adjust their plans accordingly.

3. Assistance for Small Entities

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, above.

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.

4. 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).

5. Federalism

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 determined that this rule does not have implications for federalism.

6. 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.

7. 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 expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

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.

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (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 the establishment of a safety zone. This rule is categorically excluded from further review under paragraph 34–(g) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

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, 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0701 to read as follows:

§ 165.T05–0701 Safety Zone, James River; Newport News, VA.

(a) *Definitions.* For the purposes of this section, *Captain of the Port* means the Commander, Sector Hampton Roads. *Representative* means any Coast Guard commissioned, warrant or petty officer who has been authorized to act on the behalf of the Captain of the Port. *Participants* mean individuals and vessels involved in explosives training.

(b) *Locations.* The following area is a safety zone:

(1) All waters in the vicinity of the of the James River Reserve Fleet, in the James River, within a 1500 foot radius of the M/V SS DEL MONTE in approximate position 37°06′11″ N., 076°38′40″ W. (NAD 1983).

(c) *Regulations.* (1) All persons are required to comply with the general regulations governing safety zones in § 165.23 of this part.

(2) With the exception of participants, entry into or remaining in this safety zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(3) All vessels underway within this safety zone at the time it is implemented are to depart the zone immediately.

(4) The Captain of the Port, Hampton Roads or his representative can be contacted at telephone number (757) 668–5555.

(5) The Coast Guard and designated James River Reserve Fleet security vessels enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65 Mhz) and channel 16 (156.8 Mhz).

(6) This section applies to all persons or vessels wishing to transit through the safety zone except participants and vessels that are engaged in the following operations:

(i) Enforcing laws;

(ii) Servicing aids to navigation; and

(iii) Emergency response vessels.

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

(d) *Enforcement period.* This rule will be enforced from 8 a.m. on August 17, 2015 to 4 p.m. on August 21, 2015.

Dated: July 31, 2015.

Christopher S. Keane,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. 2015–20115 Filed 8–14–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0760]

RIN 1625–AA00

Safety Zone; U.S. Army Exercise, Des Plaines River, Channahon, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Des Plaines River between mile marker 277.8 and mile marker 279.2, Channahon, IL. This safety zone is intended to restrict vessels from a portion of the Des Plaines River from August 18, 2015 to August 19, 2015, with a rain date of August 20, 2015. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with low flying aircraft and bridging operations spanning the width of the river for a U.S. Army exercise.

DATES: This rule is effective from 12:01 a.m. on August 18, 2015 to 11:59 p.m. on August 20, 2015. This rule will be enforced with actual notice from 6:30 a.m. until 6:30 p.m. on August 18, 2015 and August 19, 2015, or alternatively if postponed due to inclement weather, from 6:30 a.m. until 6:30 p.m. on August 20, 2015.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2015–0760. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact or email LT Lindsay Cook, U.S. Coast Guard Marine Safety Unit Chicago, at (630) 986–2155 or *Lindsay.N.Cook@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this temporary final 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)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking with respect to this rule because doing so would be impracticable. The final details for this event were not known to the Coast Guard until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be impracticable because it would inhibit the Coast Guard's ability to protect the public and vessels from the hazards associated with low flying aircraft and bridging operations spanning the width of the river for a U.S. Army exercise.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish safety zones: 33 U.S.C. 1231; 33 CFR 1.05–1, 160.5; Department of Homeland Security Delegation No. 0170.1.

On August 18, 2015 and August 19, 2015, the U.S. Army will conduct a bridging exercise spanning the width of the river. The Captain of the Port, Lake Michigan, has determined that the low flying aircraft and bridging operations spanning the width of the river associated with this exercise will pose a significant risk to public safety and property. This safety zone is necessary to protect the public from the hazards associated with low flying aircraft and bridging operations.

C. Discussion of the Final Rule

With the aforementioned hazards in mind, the Captain of the Port, Lake Michigan, has determined that this temporary safety zone is necessary to ensure the safety of the public and the participants during a U.S. Army exercise on a portion of the Des Plaines River from mile marker 277.8 to mile marker 279.2. This safety zone will be enforced from 6:30 a.m. until 6:30 p.m. on August 18, 2015 and August 19, 2015. If the event is postponed due to inclement weather, the safety zone will be enforced from 6:30 a.m. until 6:30 p.m. on August 20, 2015, the allotted rain date. This zone will encompass all waters of the Des Plaines River from mile marker 277.8 to mile marker 279.2.

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. The Captain of the Port or a designated on-scene representative may be contacted via VHF Channel 16.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced between the hours of 6:30 a.m. and 6:30 p.m. during a two day period. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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.

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this temporary rule on small entities. This rule will affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit on a portion of the Des Plaines River from mile marker 277.8 to mile marker 279.2 on August 18, 2015 and August 19, 2015 or on August 20, 2015.

This safety zone will not have a significant economic impact on a substantial number of small entities for the reasons cited in the *Regulatory Planning and Review* section. Additionally, before the enforcement of the zone, we will issue local Broadcast Notice to Mariners and Public Notice of Safety Zone so vessel owners and operators can plan accordingly.

3. Assistance for Small Entities

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**, above.

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.

4. 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).

5. Federalism

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 determined that this rule does not have implications for federalism.

6. 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.

7. 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.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

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.

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (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 the establishment of a safety zone and, therefore it is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

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.T09–0760 to read as follows:

§ 165.T09–0760 Safety Zone; U.S. Army Exercise, Des Plaines River, Channahon, IL.

(a) *Location.* All waters on the Des Plaines River between the mile marker 277.8 and mile marker 279.2, Channahon, IL.

(b) *Effective and Enforcement Period.* This rule is effective from 12:01 a.m. on August 18, 2015 to 11:59 p.m. on August 20, 2015. This rule will be enforced with actual notice from 6:30 a.m. until 6:30 p.m. on August 18, 2015 and August 19, 2015, or alternatively if postponed due to weather, from 6:30 a.m. until 6:30 p.m. on August 20, 2015.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port, Lake Michigan or a designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Lake Michigan or a designated on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port, Lake Michigan is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port, Lake Michigan to act on his or her behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port, Lake Michigan or an on-scene representative to obtain permission to do so. The Captain of the Port Lake Michigan or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Lake Michigan, or an on-scene representative.

Dated: August 6, 2015.

A.B. Cocanour,

Captain, U.S. Coast Guard, Captain of the Port, Lake Michigan.

[FR Doc. 2015–20251 Filed 8–14–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AO39

Animals on VA Property

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its regulation concerning the presence of animals on VA property. This final rule expands the current VA regulation to authorize the presence of service animals consistent with applicable Federal law when these animals accompany individuals with disabilities seeking admittance to property owned or operated by VA.

DATES: This rule is effective September 16, 2015.

FOR FURTHER INFORMATION CONTACT: Joyce Edmonson, RN, JD, Patient Care Services, (10P4), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (410) 637–4755. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: On November 21, 2014, VA published in the **Federal Register** (79 FR 69379) a proposed rule to amend VA regulations regarding the presence of animals on VA property. This rule authorizes the access of service animals when these animals accompany individuals with disabilities seeking admittance to VA property in a manner consistent with applicable Federal law, and clarifies the authority of a VA facility head or designee to allow non-service animals to be present on VA property.

Interested persons were invited to submit comments to the proposed rule on or before January 20, 2015, and VA received 96 comments. All of the issues raised by the commenters that concerned at least one portion of the rule can be grouped together by similar topic, and we have organized our discussion of the comments accordingly. For the reasons set forth in the proposed rule and below, we are adopting the proposed rule as final, with changes, explained below, to proposed 38 CFR 1.218(a)(11).

Multiple commenters stated that it was unclear to what groups of individuals the proposed rule would apply. One commenter specifically expressed concern as to whether a service animal that assisted a visitor of a veteran would be permitted on VA property. We clarify for these commenters that this VA regulation applies to everyone seeking access to VA property, to include employees, veterans, and visitors. The rule as proposed did not contain any limiting language to restrict applicability to only certain groups of individuals, and we therefore do not make any changes to the final rule based on these comments. Several commenters applauded the development by VA of a uniform regulation for service animal access for all VA property, and did not recommend any changes. VA appreciates these comments and believes that this regulation will allow for more consistent access of VA property by service animals.

One commenter asserted that VA should use the term ''assistance animal'' instead of ''service animals'' throughout the proposed regulation because, they assert, the term ''service animals'' is understood more narrowly in the service animal industry to refer only to those animals that assist with mobility impairments. We do not make any changes based on these comments. We disagree that the term ''assistance animal'' is better understood than ''service animal'' by those in the service animal industry. Additionally, this regulation is written for a broader audience than just those in the service animal industry, to include any member of the public that may have need to access VA property. Indeed, the term ''service animal'' as defined in the proposed rule is well understood by the general public because it is consistent with the definition of ''service animal'' in the regulations that implement the Americans with Disabilities Act (ADA). We therefore do not make any changes based on these comments. A commenter

also urged that VA use the phrase ''guide dog'' versus ''seeing eye dog.'' We do not make any changes based on this comment because, as proposed and in this final rule, ''seeing eye dog'' is replaced in § 1.218(a)(11) with the term ''service animal,'' and ''service animal'' includes those dogs trained for the purpose of assisting individuals with a sensory disability (to include visual impairments). Other commenters further asserted that the definition of ''service animal'' in proposed § 1.218(a)(11)(viii) be changed to refer to a dog that does ''work or performs tasks'' as opposed to a dog that does ''work and performs tasks.'' Particularly, commenters noted that VA used both these phrases interchangeably in proposed § 1.218(a)(11)(viii), and asserted that this was confusing. We agree with these comments, and clarify that the intent was to use only the phrase ''work or performs tasks'' throughout the definition of ''service animal.'' We therefore make changes to ensure that the phrase ''work or perform tasks'' is used consistently throughout § 1.218(a)(11)(viii).

One commenter was concerned that breed restrictions may be imposed based on a perception that certain breeds of dogs are prone to violence. This VA regulation does not impose breed restrictions, and VA will not otherwise pose breed restrictions for purposes of access of service animals on VA property. VA will only deny access to VA property or will remove a service animal from VA property based on an individual assessment in accordance with objective criteria of the risks that the individual service animal poses to the health or safety of people or other service animals. VA makes no changes based on this comment.

Several commenters sought clarification between a ''service animal'' and a ''pet,'' and whether animals other than dogs were included in the definition of ''service animal.'' As proposed, § 1.218(a)(11)(viii) defined a ''service animal'' as any dog that accompanies an individual with a disability and that is individually trained for that purpose. The definition in proposed § 1.218(a)(11)(viii) specifically excluded any species of animal other than a dog, and specifically required that the work or tasks performed by the service animal be directly related to the individual's disability. Further, § 1.218(a)(11)(viii) distinguished that the crime deterrent effects of an animal's presence, or the provision of emotional support or well-being, comfort, or companionship do not constitute ''work or tasks.'' The definition as proposed in § 1.218(a)(11)(viii) clearly excluded any animal other than a dog, and also excluded any dog that is not individually trained to assist an individual with a disability. As proposed, § 1.218(a)(11)(viii) makes clear that unless the animal is a dog that is individually trained to do something that qualifies as work or a task, the animal is a pet or other type of animal and does not qualify as a service animal. We believe the definition in proposed § 1.218(a)(11)(viii) is clear enough to exclude a ''pet,'', and we therefore do not make any changes based on these comments.

Several commenters wanted VA to permit miniature horses on VA properties. As discussed in the proposed rule, VA believes the presence of a miniature horse poses legitimate safety concerns, both to people on VA property and the miniature horse, especially on VA healthcare properties. This final rule reiterates VA's determination from the proposed rule, that, in light of a review of the multiple assessment factors, miniature horses are excluded from VA properties. We restate from the proposed rule that these assessment factors include the larger size of a miniature horse as well as their reduced predictability in behaving in accordance with typical standards of public access required of service animals. Additional factors from the proposed rule that VA considers to support the exclusion of miniature horses include elimination of horse waste, a heightened flee response of a miniature horse, the smooth flooring common to VA properties, and the likely disruptive attention a horse would receive. We therefore do not make any changes based on these comments.

Many commenters expressed concern that the proposed rule restricted access to only those dogs trained or certified by Assistance Dogs International (ADI), International Guide Dog Federation (IGDF), or one of their affiliated organizations. The proposed rule did not create such restrictions; as proposed, VA's standard for service animal access is consistent with regulations that implement the ADA and is not dependent on how the service animal was trained or by whom, but instead depends on the service animal's ability to behave in accordance with typical public access standards for public settings. Therefore, we do not make any changes based on these comments. VA notes that a service animal must be certified by ADI or IGDF as a requirement for veterans seeking service dog benefits under 38 CFR 17.148, however, those requirements for benefits do not apply to access. Conversely, several commenters asserted that service animal access to VA properties should be restricted to only those animals that are certified or trained by ADI, IGDF, or an affiliate—these commenters articulated various negative experiences where a ''fake service animal'' threatened their person, their service animal, or another person while on VA property or other property. VA recognizes that these commenters have legitimate concerns related to dogs that are not appropriately trained possibly being able to access VA property under the guise of a ''service dog,'' because VA will not be requiring any proof of training or certification for purposes of access. However, the lack of such a documentation requirement is consistent with regulations that implement the ADA, and otherwise provides the benefit of the doubt to individuals with disabilities unless the service animal's behavior necessitates that access be denied or the service animal be removed. VA does not make any changes based on these comments, but we stress that § 1.218(a)(11)(ii) still provides for removal of a service animal from certain areas on VA property if the animal exhibits behavior or other signs that it is a threat to the health or safety of individuals or other service animals on VA property.

Several commenters objected to the requirements in proposed § 1.218(a)(11)(vii) to provide proof of a service animal's good health when an individual will be accompanied by a service animal while receiving treatment in a Veterans Health Administration (VHA) residential program. Some of these commenters alluded to an administrative burden of ''registering'' a service animal to obtain access to the VA property. We clarify for these commenters that § 1.218(a)(11)(vii) only applies to situations where an individual would be accompanied by a service animal for the duration of his or her treatment in a VHA residential program—these documentation requirements would not apply for more general access to a VA property, such as to receive outpatient care provided by VA. The presentation of certain records as proof of an animal's health required in § 1.218(a)(11)(vii) is necessary when a service animal will have routine and constant interaction with employees, veterans, patients, and visitors over the course of an extended period of time in a residential setting, so that VA may ensure patient care, patient safety, and infection control standards are met. However, we do agree with the commenters who noted that some of the

requirements in § 1.218(a)(11)(vii) as proposed could create an undue administrative burden on both individuals receiving treatment as well as VA staff. We therefore make changes in the final rule to remove § 1.218(a)(11)(vii)(A)–(C), and to revise § 1.218(a)(11)(vii) to require that the individual receiving treatment in a residential program must only provide documentation that confirms that the service animal has a current rabies vaccine and current core canine vaccines. We further revise the conditions in § 1.218(a)(11)(vii) related to when a rabies vaccine and core canine vaccines are considered ''current'' to require ''a current rabies vaccine as determined by state and local public health requirements, and current core canine vaccines as dictated by local veterinary practice standards (*e.g.* distemper, parvovirus, and adenovirus-2).'' These changes will retain the requirement for documentation of basic canine vaccinations that we believe is necessary to ensure the service animal is in good health, while providing more flexibility of those required vaccinations in accordance with local requirements. These revisions will also remove the requirement for proof of a comprehensive exam within the past 12 months, as well as remove the requirement that an individual must otherwise confirm in writing that the service animal is healthy. We believe that the revised documentation requirements in § 1.218(a)(11)(vii) now relate only to the basic canine vaccines that an the individual would have merely as a function of being a responsible dog owner, and therefore providing such documentation to VA for confirmation is not burdensome. We make similar changes to the documentation requirements related to the health of non-service animals in § 1.218(a)(11)(ix)(C)–(E), specifically to clarify that the prophylactic medication requirement for non-service animals applies only to parasite control medications (*e.g.* monthly flea and tick prevention), and to clarify that the health requirements for non-service animals are consistent with local veterinary practice standards.

One commenter suggested that the mere presence of a flea or tick on a service animal should not be grounds for removal of a service animal under § 1.218(a)(11)(ii)(C)(2), particularly for individuals being treated in VA residential settings. VA does not make any changes based on this comment. We reiterate from the proposed rule that the presence of a flea or tick poses a threat to the health and safety of others, as fleas, ticks, and other parasites can be spread by physical contact and close proximity and can reproduce quickly and in great volume to create infestation conditions that are much more difficult to remediate, versus removing a service animal with visible external parasites. We note, however, that under § 1.218(a)(11)(ii)(C), VA staff must complete an individualized assessment based on objective indications, such as external signs of parasites, to ascertain the severity of risk to the health or safety of people or other service animals.

Several commenters suggested that VA revise § 1.218(a)(11)(viii) to permit service dogs in training to access VA property. Some of these commenters reasoned that a service dog in training could be well trained enough to dependably behave safely in public settings, even without having fully completed their training. Other commenters expressed that VA properties could be used as training opportunities for service animals. VA seeks to maintain a safe and therapeutic environment at its properties. In a complex hospital environment, we believe that service animals should be fully trained and a ''service animal in training'' is not fully trained. We therefore do not revise § 1.218(a)(11)(viii) to permit service animals in training.

Several commenters inquired as to how VA's service animal access rule would be enforced, particularly with regard to staff training. Some commenters expressed concerns about ''fake service animals'' interfering with the need for people and service animals to safely access VA properties. Others expressed concerns that VA's proposed rule would establish a barrier to access or expressed concern regarding the authority of varying facility directors to devise implementation criteria that would restrict access outside of the proposed rule. VA does not make any changes based on these comments. The final rule establishes a set of standardized criteria that can be uniformly enforced on VA property, and removes variation amongst individual facilities that existed prior to this final rule. A service animal meeting VA's requirements under this final rule will not be subject to any barrier to access. And once on VA property, service animals are subject to the same terms, conditions and regulations that govern the admission of the public to VA property, to include certain exceptions on VHA properties to ensure patient care, patient safety, and infection control standards are not compromised. Therefore, service animals would only be denied access or removed if, based on an individualized assessment that is subject to objective indications in the final rule to ascertain severity of risk, there is cause for access denial or removal. VA anticipates that in most cases concerns related to access and removal will be communicated by veterans, employees, or visitors to VA staff members (including security and law enforcement) who will manage any concerns and facilitate an appropriate response. VA anticipates all appropriate staff members will be trained on what is and what is not allowed under this regulation and how it should be implemented.

Several commenters expressed concern about the requirement in proposed § 1.218(a)(11)(i) that the service animal be in a guiding harness or on a leash, as well as under the control of the individual with a disability, at all times while on VA property. These commenters asserted that multiple disabilities might prevent an individual from physically controlling a service animal via a harness or leash, or that the service animal's presence on a leash or other tether at all times might prevent that service animal from completing work or tasks they are trained to perform. Further, some commenters urged VA to adopt a standard that mimics that of the regulations that implement the ADA, whereby control over the service animal by the handler can be in the form of voice control. VA agrees with these comments, and amends § 1.218(a)(11)(i) to incorporate comparable language to that used in the regulations that implement the ADA. *Cf.* 28 CFR 36.302(c)(4).

Likewise, after considering related comments, VA recognizes that individuals with disabilities may require the assistance of an alternate handler to control the service animal while on VA property. The need for an alternate handler may arise when the individual with the disability is unable to control the service animal because of the care the individual receives; or when the service animal, individual with a disability, and the alternate handler routinely operate as part of a team when accessing public areas. For this reason, VA amends § 1.218(a)(11)(i) and (a)(11)(ii)(A) to allow for an alternate handler to also be in control of the service animal. Specifically, § 1.218(a)(11)(i) will state that a service animal shall be under the control of the person with the disability or an alternate handler at all times while on VA property. Section 1.218(a)(11)(i) will also state that a service animal shall have a harness, leash, or other tether,

unless either the handler is unable because of a disability to use a harness, leash, or other tether, or the use of a harness, leash, or other tether would interfere with the service animal's safe, effective performance of work or tasks, in which case the service animal must be otherwise under the handler's control (*e.g.,* voice control, signals, or other effective means). We reiterate, that at no time is any VA employee to be responsible for the control of the service animal, as set forth in § 1.218(a)(11)(i).

Several commenters inquired into whose responsibility is it to clean up animal waste and if VA properties have to designate an area for animals to relieve themselves. Commensurate with the requirements for access is a properly housebroken service animal. Should a service animal relieve bowel or bladder on VA property, it is the responsibility of the handler or the alternate handler to properly dispose of the waste in accordance with standards appropriate for public settings. VA again notes that at no time is any employee to be responsible to control a service animal and part of the access requirements is that an animal is housebroken. VA makes no change based on this comment.

Several commenters objected to the absolute prohibition of service animal access to certain areas of VHA property in proposed 1.218(a)(11)(iii), citing contrary standards that permit such access in regulations that implement the ADA as well as guidance issued by the Centers for Disease Control and Prevention (CDC). Particularly, commenters objected to the categorical exclusion of service animals from inpatient hospital settings to include locked mental health units (in proposed § 1.218(a)(11)(iii)(C)), and from patient rooms or treatment areas where patients may have an animal allergy or phobia (in proposed § 1.218(a)(11)(iii)(E)). VA cited three examples of acute inpatient hospital settings in proposed § 1.218(a)(11)(iii)(C) (intensive care units, stabilization units, and locked mental health units) in a representative but not exhaustive list of areas that could be covered by this exclusion. In light of the comments received, VA revises § 1.218(a)(11)(iii)(C) to remove these examples, and instead qualify the exclusion of service animals in acute inpatient settings to exclude such animals when their presence is not part of a documented treatment plan. VA agrees with the commenters that there are scenarios in which a service animal on any of the specific areas in proposed § 1.218(a)(11)(iii)(C) may provide its services when the individual being treated or an alternate handler can control a service animal as part of a treatment plan established by the clinical care team. Although VA used CDC guidance to justify the area-based exclusions in proposed § 1.218(a)(11)(iii)(C) (see 79 FR 69379, 69381), VA believes that this revision is still consistent with CDC's guidance because the service animal would not be permitted to access the inpatient area if not part of a documented treatment plan. The animal would require a staff assessment under § 1.218(a)(11)(ii)(C) to evaluate any threat to the health or safety of patients or staff. A service animal could still be removed under § 1.218(a)(11)(ii) if it presented a risk to patient safety or infection control standards after gaining access to an acute inpatient setting. For these same reasons, VA removes proposed § 1.218(a)(11)(iii)(E), the prohibition of the presence of service animals in patient rooms or areas where a patient may have an animal allergy or phobia. Again, a service animal could be removed from such an area if the animal posed a risk to patient safety or health, under § 1.218(a)(11)(ii). By removing proposed § 1.218(a)(11)(iii)(E), we will renumber proposed § 1.218(a)(11)(iii)(F) and (iii)(G) as (iii)(E) and (iii)(F), respectively.

However, VA will not remove all categorical area-based exclusions of service animals on VHA property from proposed § 1.218(a)(11)(iii). VA's healthcare facilities reflect evidence based standards governing safe operation of a healthcare facility, patient care, and infection control. Consistent with CDC guidance, VA still finds certain locations such as operating rooms, surgical suites, areas where invasive procedures are being performed, decontamination, sterile processing, sterile storage areas, food preparation areas (not to include public food service areas), and any areas where protective barrier measures are required, to be inappropriate environments for a service animal. One commenter recommended removing the representative examples in proposed § 1.218(a)(11)(iii)(A)–(C) as redundant of places where protective barrier measures are required. We decline to remove these examples because they add clarity regarding the types of areas where access must be restricted to ensure patient care, patient safety or infection control standards are not compromised. While we will retain these area-based exclusions and the examples provided in the final rule, in response to comments we will revise § 1.218(a)(11)(iii)(F) as proposed, renumbered as § 1.218(a)(11)(iii)(E), to include the clarifying parenthetical ''(not to include public food service areas).'' We will also revise § 1.218(a)(11)(iii)(G) as proposed, renumbered as § 1.218(a)(11)(iii)(F), to refer to areas ''where personal protective clothing must be worn or barrier protective measures must be taken to enter,'' instead of referring to areas that require ''personal protective equipment'' to be worn. We agree with commenters that ''personal protective equipment'' in proposed § 1.218(a)(11)(iii)(G) could be interpreted to encompass even the wearing of basic equipment by patients, staff, or visitors like paper face masks or examination gloves, which could qualify nearly any area of a VHA medical facility as categorically excluding the presence of a service animal. The revisions to proposed § 1.218(a)(11)(iii)(G) (§ 1.218(a)(11)(iii)(F) as renumbered) more accurately describe the types of areas that a service animal will be restricted from entering.

We emphasize that even with these changes to the area-based exclusions in § 1.218(a)(11)(iii), a specific service animal may still be individually denied access or removed if it does not meet the standards in § 1.218(a)(11)(i) and (a)(11)(ii), namely that the animal must be controlled (by the individual or an alternate handler that is not a VA employee), be housebroken, and not pose a threat to the health and safety of people or other service animals.

Several commenters expressed concerns regarding the provision of service dogs, service dog training, and service dog benefits by VA. Particularly, some commenters asserted that VA should assist veterans to obtain a service dog and have such a dog trained and certified. These comments are beyond the scope of this rule, and we therefore do not make any changes. We note, however, that the provision of service dog benefits by VA is regulated at 38 CFR 17.148. Other commenters noted the benefits of service animals for the treatment of PTSD, but did not necessarily suggest any changes to the proposed rule. Again, these comments are beyond the scope of this rule, and we therefore do not make any changes. Some commenters requested that the final rule provide examples of what VA considers to be ''work'' or ''tasks'' that a service animal may be trained to perform, either in the preamble or through revisions to the regulation text. Commenters noted that such examples would be particularly helpful for a service animal that might assist an individual with a mental disability or illness. We decline to make revisions to

the regulation text or provide examples in the preamble of this final rule. However, we do provide as reference here the supplemental guidance issued by the Department of Justice when it last issued regulations on this subject in 2010, specifically on what constitutes ''work or tasks'' that a service animal may provide (see Appendix A to 28 CFR part 36, Guidance on Revisions to ADA Regulation on Nondiscrimination on the Basis of Disability by Public Accommodations and Commercial Facilities, 75 FR 56236, 56258). This reference provides examples of work or tasks that VA understands to be performed by service animals for individuals with disabilities so that such individuals may better navigate public spaces. By providing this reference of examples of work and tasks in the context of public access, VA is not expressing a position on the efficacy of such dogs for the treatment of the disabilities of the individuals.

One commenter urged VA to include emotional support animals in the definition of ''service animal'' in § 1.218(a)(11)(viii) as proposed. The commenter asserted that because many veterans with PTSD use emotional support animals in their homes, that refusing access to emotional support animals on VA property could discourage use of VA services by such veterans. This same commenter also made a reference to Department of Housing and Urban Development (HUD) regulations and guidance that create exclusions for public housing's ''no pet'' policies for certain animals, to include permitting access for emotional support animals in applicable circumstances, and suggested that VA consider developing a similar rule regarding emotional support animal access on VA property. Another commenter suggested adopting HUD's approach in the context of VA's residential treatment programs. VA does not disagree that some veterans may use emotional support animals, nor disagree with the commenters' subjective accounts that such animals have improved the quality of their lives. However, the HUD regulations and guidance referenced by the commenters appropriately apply in the context of public housing. In particular, the HUD regulations and guidance do not require an animal to be individually trained to do work or perform tasks for the benefit of the individual with a disability. However, there is a distinction between the presence of an animal in public areas and the functions that animal performs to enable an individual to use public services and public accommodations (service animal), as compared to the presence and use of a comfort or emotional support animal in the home (emotional support animal). Regarding VHA's residential treatment programs, these programs involve shared spaces amongst multiple veterans, where there is an active treatment component that involves the participation of not only the veterans but also treatment providers as well as other members of the public at times. Therefore, we interpret VHA residential programs to be public treatment spaces (just as the other areas of VHA property that are specified in this final rule), rather than a residential space analogous to the HUD public housing context. We therefore do not make any changes based on these comments.

Commenters expressed concern about the area-based restrictions for property under the control of the National Cemetery Administration (NCA) in proposed § 1.218(a)(11)(iv). We interpret such comments to be the result of a misunderstanding by commenters that new restrictions were being created in the proposed rule when in fact the proposed area-based restrictions reflect existing restrictions on NCA property in accordance with rules requiring access on the same terms, conditions, and regulations that generally govern admission of the public to the property. That is, the proposed and final rules only clarify that where an individual may not access NCA property (*i.e.,* in NCA construction or maintenance sites, or in NCA open interment areas), so, too, a service animal may not access such property. This rule does not affect the right of an individual to be accompanied by their service animal on NCA grounds in those areas where the general public is permitted. However, these comments raise the possibility that the provision regarding restriction of access to open interment areas may be perceived as overly restrictive. We have, therefore, made a change to § 1.218(a)(11)(iv)(A) to remove the reference to columbaria (as columbaria pose minimal safety issues), and to indicate that individuals may be permitted to observe an individual interment or inurnment accompanied by a service animal. This change will allow family or representatives (such as clergy), accompanied by their service animals, to observe an interment or inurnment when requested and when such observation can be safely accommodated.

VA makes one technical correction in § 1.218(a)(11)(viii). In the last sentence, VA is replacing ''of this chapter'' with a complete citation ''38 CFR 17.148.'' VA also makes several minor, non-substantive edits for clarity such as removing the first commas appearing in proposed § 1.218(a)(11)(ix)(C) and (D), replacing the word ''on'' with the word ''in'' three places in § 1.218(a)(11)(ix)(E) in reference to VA Community Living Centers, and adding the clarifying phrase ''with respect to an individual'' to the definition of a disability in § 1.218(a)(11)(x).

One commenter asked for clarification if animals other than dogs can participate in Animal Assisted Activities (AAA) or Animal Assisted Therapy (AAT) programs under § 1.218(a)(11)(ix)(C) and (ix)(D) as proposed. Unlike service animals under the proposed and final rules, there is no species restriction for AAA or AAT animals, and AAA or AAT animals are permitted on VHA property only at the discretion of the VA facility head or designee. Should an AAA or AAT animal that is not a dog meet the requirements in § 1.218(a)(11)(ix)(C) and (D), a VA facility head or designee may grant that animal access to VA property. Another commenter suggested that VA allow for pets to visit patients in unique circumstances such as end-of-life situations. As with other species of animals, there is no categorical restriction for AAA or AAT animals that would necessarily exclude a personal pet in an end-of-life or other special circumstance. Should an animal serve an AAA or AAT purpose and meet the requirements in § 1.218(a)(11)(ix)(C) and (D), a VA facility head or designee may grant that animal access to VA property. In addition, a commenter suggested that AAA and AAT animals be allowed on VA property only when their handler or organization has liability insurance. We do not disagree that liability insurance would be a sensible requirement, particularly as AAA is often conducted in group settings. However, VA believes that any liability insurance would be better addressed outside of a regulatory requirement by the VA facility head or designee and the AAA or AAT handler or organization prior to establishing a particular program at a facility. VA makes no changes based on these comments.

For all of the reasons noted above, VA is adopting the rule as final with changes as noted to 38 CFR 1.218.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance

must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

This final rule includes a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) that requires approval by the Office of Management and Budget (OMB). Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking action to OMB for review.

OMB assigns a control number for each collection of information it approves. VA 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. Section 1.218(a)(11) contains a collection of information under the Paperwork Reduction Act of 1995. OMB has approved the information collection requirement in this section as an emergency clearance under control number 2900–0831. This emergency clearance expires on December 31, 2015, before which time VA will submit to OMB a request for permanent clearance.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule directly affects only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the final regulatory flexibility analysis requirements of 5 U.S.C. 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by OMB, unless OMB waives such review, as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date.''

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an 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. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.007, Blind Rehabilitation Centers; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; and 64.011, Veterans Dental Care.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors II, Chief of Staff, Department of Veterans Affairs, approved this document on June 5, 2015, for publication.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Cemeteries, Government property, Security measures.

Dated: June 19, 2015.

Michael Shores,

Chief Impact Analyst, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, VA amends 38 CFR part 1 as follows:

PART 1—GENERAL PROVISIONS

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

Authority: 38 U.S.C. 501(a), and as noted in specific sections.

■ 2. Revise § 1.218(a)(11) to read as follows:

§ 1.218. Security and law enforcement at VA facilities.

(a) * * *

(11) *Animals.* (i) Service animals, as defined in paragraph (a)(11)(viii) of this section, are permitted on VA property when those animals accompany individuals with disabilities and are trained for that purpose. A service animal shall be under the control of the person with the disability or an alternate handler at all times while on VA property. A service animal shall have a harness, leash, or other tether, unless either the handler is unable because of a disability to use a harness, leash, or other tether, or the use of a harness, leash, or other tether would interfere with the service animal's safe, effective performance of work or tasks, in which case the service animal must be otherwise under the handler's control (*e.g.,* voice control, signals, or other effective means). VA is not responsible for the care or supervision of a service animal. Service animal presence on VA property is subject to the same terms, conditions, and regulations as generally govern admission of the public to the property.

(ii) A service animal will be denied access to VA property or removed from VA property if:

(A) The animal is not under the control of the individual with a disability or an alternate handler;

(B) The animal is not housebroken. The animal must be trained to eliminate its waste in an outdoor area; or

(C) The animal otherwise poses a risk to the health or safety of people or other service animals. In determining whether

an animal poses a risk to the health or safety of people or other service animals, VA will make an individualized assessment based on objective indications to ascertain the severity of the risk. Such indications include but are not limited to:

(*1*) External signs of aggression from the service animal, such as growling, biting or snapping, baring its teeth, lunging; or

(*2*) External signs of parasites on the service animal (*e.g.* fleas, ticks), or other external signs of disease or bad health (*e.g.* diarrhea or vomiting).

(iii) Service animals will be restricted from accessing certain areas of VA property under the control of the Veterans Health Administration (VHA properties) to ensure patient care, patient safety, or infection control standards are not compromised. Such areas include but are not limited to:

(A) Operating rooms and surgical suites;

(B) Areas where invasive procedures are being performed;

(C) Acute inpatient hospital settings when the presence of the service animal is not part of a documented treatment plan;

(D) Decontamination, sterile processing, and sterile storage areas;

(E) Food preparation areas (not to include public food service areas); and

(F) Any areas where personal protective clothing must be worn or barrier protective measures must be taken to enter.

(iv) Service animals will be restricted from accessing certain areas of VA property under the control of the National Cemetery Administration (NCA properties) to ensure that public safety, facilities and grounds care, and maintenance control are not compromised. Such areas include but are not limited to:

(A) Open interment areas, except as approved to observe an individual interment or inurnment.

(B) Construction or maintenance sites; and

(C) Grounds keeping and storage facilities.

(v) If a service animal is denied access to VA property or removed from VA property in accordance with (a)(11)(ii) of this section, or restricted from accessing certain VA property in accordance with paragraphs (a)(11)(iii) and (iv) of this section, then VA will give the individual with a disability the opportunity to obtain services without having the service animal on VA property.

(vi) Unless paragraph (a)(11)(vii) of this section applies, an individual with a disability must not be required to provide documentation, such as proof that an animal has been certified, trained, or licensed as a service animal, to gain access to VA property accompanied by the service animal. However, an individual may be asked if the animal is required because of a disability, and what work or task the animal has been trained to perform.

(vii) An individual with a disability, if such individual will be accompanied by the service animal while receiving treatment in a VHA residential program, must provide VA with documentation that confirms the service animal has had a current rabies vaccine as determined by state and local public health requirements, and current core canine vaccines as dictated by local veterinary practice standards (*e.g.* distemper, parvovirus, and adenovirus-2).

(viii) A service animal means any dog that is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability. Other species of animals, whether wild or domestic, trained or untrained, are not service animals for the purposes of this definition. The work or tasks performed by a service animal must be directly related to the individual's disability. The crime deterrent effects of an animal's presence and the provision of emotional support, well-being, comfort, or companionship do not constitute work or tasks for the purposes of this definition. Service dogs in training are not considered service animals. This definition applies regardless of whether VA is providing benefits to support a service dog under 38 CFR 17.148.

(ix) Generally, animals other than service animals (''non-service animals'') are not permitted to be present on VA property, and any individual with a non-service animal must remove it. However, a VA facility head or designee may permit certain non-service animals to be present on VA property for the following reasons:

(A) Animals may be permitted to be present on VA property for law enforcement purposes;

(B) Animals under the control of the VA Office of Research and Development may be permitted to be present on VA property;

(C) Animal-assisted therapy (AAT) animals may be permitted to be present on VHA property when the presence of such animals would not compromise patient care, patient safety, or infection control standards. AAT is a goal-directed clinical intervention, as provided or facilitated by a VA therapist or VA clinician, that incorporates the use of an animal into the treatment regimen of a patient. Any AAT animal present on VHA property must facilitate achievement of patient-specific treatment goals, as documented in the patient's treatment plan. AAT animals must be up to date with all core vaccinations or immunizations, prophylactic parasite control medications, and regular health screenings as determined necessary by a licensed veterinarian consistent with local veterinary practice standards. Proof of compliance with these requirements must be documented and accessible in the area(s) where patients receive AAT.

(D) Animal-assisted activity (AAA) animals may be permitted to be present on VHA property when the presence of such animals would not compromise patient care, patient safety, or infection control standards. AAA involves animals in activities to provide patients with casual opportunities for motivational, educational, recreational, and/or therapeutic benefits. AAA is not a goal-directed clinical intervention that must be provided or facilitated by a VA therapist or clinician, and therefore is not necessarily incorporated into the treatment regimen of a patient or documented in the patient's medical record as treatment. AAA animals must be up to date with all core vaccinations or immunizations, prophylactic parasite control medications, and regular health screenings as determined necessary by a licensed veterinarian consistent with local veterinary practice standards. Proof of compliance with these requirements must be documented and accessible in the area(s) where patients may participate in AAA.

(E) Animals participating in a VA Community Living Center (CLC) residential animal program or a Mental Health Residential Rehabilitation Treatment Program (MHRRTP) may be permitted to be present on VHA property, when the presence of such animals would not compromise patient care, patient safety, or infection control standards. A residential animal program in a VA CLC or a MHRRTP is a program that uses the presence of animals to create a more homelike environment to foster comfort for veterans, while also stimulating a sense of purpose, familiarity, and belonging. Any VA CLC or MHRRTP residential animal present on VHA property must facilitate achievement of therapeutic outcomes (such as described above), as documented in patient treatment plans. Residential animals in a VA CLC or MHRRTP must be up to date with all core vaccinations and immunizations, prophylactic parasite control

medications, and regular health screenings as determined necessary by a licensed veterinarian consistent with local veterinary practice standards. Proof of compliance with these requirements must be documented and accessible in the VA CLC or MHRRTP.

(F) Animals may be present on NCA property for ceremonial purposes during committal services, interments, and other memorials, if the presence of such animals would not compromise public safety, facilities and grounds care, and maintenance control standards.

(x) For purposes of this section, a disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of the individual; a record of such an impairment; or being regarded as having such an impairment.

(OMB has approved the information collection requirements in this section under control number XXXX–XXXX.)

* * * * *

(Authority: 38 U.S.C. 901, 40 U.S.C. 3103)

[FR Doc. 2015–20182 Filed 8–14–15; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[EPA–HQ–OAR–2015–0208; FRL–9931–94–OAR]

RIN 2060–AS64

Approval of North Carolina's Request To Relax the Federal Reid Vapor Pressure Gasoline Volatility Standard for Mecklenburg and Gaston Counties

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a request from the state of North Carolina for the EPA to relax the Reid Vapor Pressure (RVP) standard applicable to gasoline introduced into commerce from June 1 to September 15 of each year for Mecklenburg and Gaston counties. Specifically, the EPA is approving amendments to the regulations to allow the RVP standard for the two counties to rise from 7.8 pounds per square inch (psi) to 9.0 psi for gasoline. The EPA has determined that this change to the federal RVP regulation is consistent with the applicable provisions of the Clean Air Act (CAA). This action is being taken without prior proposal because the EPA believes that this rulemaking is noncontroversial for the reasons set forth in this preamble, and due to the limited scope of this action.

DATES: This rule is effective on October 16, 2015 without further notice, unless EPA receives adverse comment by September 16, 2015. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2015–0208, to the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Patty Klavon, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, Michigan, 48105; telephone number: (734) 214–4476; fax number: (734) 214–4052; email address: *klavon.patty@epa.gov.*

SUPPLEMENTARY INFORMATION:

The contents of this preamble are listed in the following outline:

I. General Information

A. Why is the EPA issuing a direct final rule?

The EPA is making this revision as a direct final rule without prior proposal because the EPA views this revision as noncontroversial and anticipates no adverse comment. The rationale for this rulemaking is described in detail below. In the Proposed Rules section of this **Federal Register**, the EPA is publishing a separate document that will serve as the proposal to approve this revision to the RVP gasoline standard that applies in Mecklenburg and Gaston counties should adverse comments be filed. If the EPA receives no adverse comment, the EPA will not take further action on the proposed rule. If the EPA receives adverse comment on this rule or any portion of this rule, the EPA will withdraw the direct final rule or the portion of the rule that received adverse comment. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this rulemaking. Any parties interested in commenting must do so at this time.

B. Does this action apply to me?

Entities potentially affected by this rule are fuel producers and distributors who do business in North Carolina.

Examples of potentially regulated entities	NAICS [1] codes
Petroleum refineries	324110
Gasoline Marketers and Distributors	424710 424720
Gasoline Retail Stations	447110
Gasoline Transporters	484220 484230

The above table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. The table lists the types of entities of which the EPA is aware that potentially could be affected by this rule. Other types of entities not listed on the table could also be affected by this rule. To determine whether your organization could be affected by this rule, you should carefully examine the regulations in 40 CFR 80.27. If you have questions regarding the applicability of this action to a particular entity, call the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

[1] North American Industry Classification System.

C. What should I consider as I prepare my comments?

1. Submitting CBI

Do not submit CBI to the 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 the EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for Preparing Your Comments

When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The EPA may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

3. Docket Copying Costs

You may be required to pay a reasonable fee for copying docket materials.

II. Action Being Taken

This direct final rule approves a request from the state of North Carolina to change the summertime gasoline RVP standard for Mecklenburg and Gaston counties from 7.8 psi to 9.0 psi by amending the EPA's regulations at 40 CFR 80.27(a)(2). In a previous rulemaking, the EPA approved a redesignation request and maintenance plan for the Charlotte-Gastonia-Salisbury, North Carolina 2008 ozone area (''the Charlotte area'') and a CAA section 110(l) non-interference demonstration that relaxing the federal RVP gasoline requirement from 7.8 psi to 9.0 psi for gasoline sold from June 1 to September 15 of each year in Mecklenburg and Gaston counties would not interfere with maintenance of the national ambient air quality standards (NAAQS) in the Charlotte area. Mecklenburg and Gaston counties are part of the Charlotte area. For more information on North Carolina's redesignation request and maintenance plan for the Charlotte area, please refer to Docket ID. No. EPA–R04–OAR–2015–0275 for the rulemaking that was signed on July 17, 2015. The preamble for this rulemaking is organized as follows: Section III. provides the history of the federal gasoline volatility regulation. Section IV. describes the policy regarding relaxation of volatility standards in ozone nonattainment areas that are redesignated as attainment areas. Section V. provides information specific to North Carolina's request for Mecklenburg and Gaston counties. Finally, Section VI. presents the final action in response to North Carolina's request.

III. History of the Gasoline Volatility Requirement

On August 19, 1987 (52 FR 31274), the EPA determined that gasoline nationwide was becoming increasingly volatile, causing an increase in evaporative emissions from gasoline-powered vehicles and equipment. Evaporative emissions from gasoline, referred to as volatile organic compounds (VOC), are precursors to the formation of tropospheric ozone and contribute to the nation's ground-level ozone problem. Exposure to ground-level ozone can reduce lung function, thereby aggravating asthma and other respiratory conditions, increase susceptibility to respiratory infection, and may contribute to premature death in people with heart and lung disease.

The most common measure of fuel volatility that is useful in evaluating gasoline evaporative emissions is RVP. Under CAA section 211(c), the EPA promulgated regulations on March 22, 1989 (54 FR 11868) that set maximum limits for the RVP of gasoline sold during the regulatory control periods that were established on a state-by-state basis in the final rule. The regulatory control periods addressed the portion of the year when peak ozone concentrations were expected. These regulations constituted Phase I of a two-phase nationwide program, which was designed to reduce the volatility of gasoline during the high ozone season. On June 11, 1990 (55 FR 23658), the EPA promulgated more stringent volatility controls as Phase II of the volatility control program. These requirements established maximum gasoline RVP standards of 9.0 psi or 7.8 psi (depending on the state, the month, and the area's initial ozone attainment designation with respect to the 1-hour ozone NAAQS.)

The 1990 CAA Amendments established a new section 211(h) to address fuel volatility. CAA section 211(h) requires the EPA to promulgate regulations making it unlawful to sell, offer for sale, dispense, supply, offer for supply, transport, or introduce into commerce gasoline with an RVP level in excess of 9.0 psi during the high ozone season. CAA section 211(h) also prohibits the EPA from establishing a volatility standard more stringent than 9.0 psi in an attainment area, except that the EPA may impose a lower (more stringent) standard in any former ozone nonattainment area redesignated to attainment.

On December 12, 1991 (56 FR 64704), the EPA modified the Phase II volatility regulations to be consistent with CAA section 211(h). The modified regulations prohibited the sale of gasoline with an RVP above 9.0 psi in all areas designated attainment for ozone, effective January 13, 1992. For areas designated as nonattainment, the regulations retained the original Phase II standards published on June 11, 1990 (55 FR 23658), which included the 7.8 psi ozone season limitation for certain areas. As stated in the preamble to the Phase II volatility controls and reiterated in the proposed change to the volatility standards published in 1991, the EPA will rely on states to initiate changes to their respective volatility programs. The EPA's policy for approving such changes is described below in Section IV. of this action.

The state of North Carolina has initiated this change by requesting that the EPA relax the 7.8 psi gasoline RVP standard to 9.0 psi for Mecklenburg and Gaston counties, which are subject to the 7.8 gasoline RVP requirement during the summertime ozone season. Accordingly, the state of North Carolina provided a technical demonstration showing that relaxing the federal gasoline RVP requirements in the two counties from 7.8 psi to 9.0 psi would not interfere with maintenance of the NAAQS in the Charlotte area or with any other applicable CAA requirement.

IV. The EPA's Policy Regarding Relaxation of Gasoline Volatility Standards in Ozone Nonattainment Areas That Are Redesignated as Attainment Areas

As stated in the preamble for the EPA's amended Phase II volatility standards (56 FR 64706), any change in the volatility standard for a nonattainment area that was subsequently redesignated as an attainment area must be accomplished through a separate rulemaking that revises the applicable standard for that area. Thus, for former 1-hour ozone nonattainment areas where the EPA mandated a Phase II volatility standard of 7.8 psi RVP in the December 12, 1991 rulemaking, the federal 7.8 psi RVP gasoline requirement remains in effect, even after such an area is redesignated to attainment, until a separate rulemaking is completed that relaxes the federal RVP gasoline standard in that area from 7.8 psi to 9.0 psi.

As explained in the December 12, 1991 rulemaking, the EPA believes that relaxation of an applicable gasoline RVP standard is best accomplished in conjunction with the redesignation process. In order for an ozone nonattainment area to be redesignated as an attainment area, CAA section 107(d)(3) requires the state to make a showing, pursuant to CAA section 175A, that the area is capable of maintaining attainment for the ozone NAAQS for ten years. Depending on the area's circumstances, this maintenance plan will either demonstrate that the area is capable of maintaining attainment for ten years without the more stringent gasoline volatility standard or that the more stringent gasoline volatility standard may be necessary for the area to maintain its attainment with the ozone NAAQS. Therefore, in the context of a request for redesignation, the EPA will not relax the gasoline volatility standard unless the state requests a relaxation and the maintenance plan demonstrates to the satisfaction of the EPA that the area will maintain attainment for ten years without the need for the more stringent volatility standard.

North Carolina requested relaxation of the federal RVP gasoline standard from 7.8 psi to 9.0 psi for Mecklenburg and Gaston counties concurrent with its request that the EPA approve a redesignation request and maintenance plan for the Charlotte area for the 2008 ozone NAAQS.

V. North Carolina's Request To Relax the Federal Gasoline RVP Requirement for Mecklenburg and Gaston Counties

On March 11, 2015, the state of North Carolina, through the North Carolina Department of Environment and Natural Resources (NCDENR), submitted a redesignation request and maintenance plan for the Charlotte area, which was classified as Marginal for the 2008 ozone NAAQS. Mecklenburg and Gaston counties are part of the Charlotte area. Additionally, the state submitted a CAA section 110(l) non-interference demonstration that removal of the federal RVP requirement of 7.8 psi for gasoline during the summertime ozone season in Mecklenburg and Gaston counties would not interfere with maintenance of any NAAQS, including the 2008 ozone NAAQS. Specifically, the state provided a technical demonstration showing that relaxing the federal gasoline RVP requirement in the two counties from 7.8 psi to 9.0 psi would not interfere with maintenance of the ozone NAAQS in the Charlotte area or with any other applicable requirement of the CAA.

In a rulemaking that was signed on July 17, 2015, the EPA evaluated and approved North Carolina's March 11, 2015 redesignation request and maintenance plan for the Charlotte area. See Docket ID. No. EPA–R04–OAR–2015–0275. In a separate rulemaking signed on July 17, 2015, the EPA approved North Carolina's non-interference demonstration for Mecklenburg and Gaston counties. See Docket ID. No. EPA–R04–OAR–2015–0260.[2]

Both rulemakings were subject to public notice-and-comment. The EPA received two comments on the redesignation request and maintenance plan rulemaking, and those comments were addressed in the final rule for that rulemaking. The comments received can be found in the docket for that rulemaking (Docket ID. No. EPA–R04–OAR–2015–0275). No comments were received on the non-interference demonstration for Mecklenburg and Gaston counties (Docket ID. No. EPA–R04–OAR–2015–0260).

In this action, the EPA is taking the second and final step in the process to approve North Carolina's request to relax the summertime ozone season gasoline RVP standard for Mecklenburg and Gaston counties from 7.8 psi to 9.0 psi. Specifically, the EPA is amending the applicable gasoline RVP standard from 7.8 psi to 9.0 psi provided at 40 CFR 80.27(a)(2) for the two counties. This action to approve North Carolina's request to relax the summertime ozone season RVP standard for Mecklenburg and Gaston counties from 7.8 psi to 9.0 psi is based on the EPA's previous approval of North Carolina's March 11, 2015 redesignation request and maintenance plan for the Charlotte area, as well as the non-interference demonstration. This approval is also based on the fact that the Charlotte area is currently in attainment for both the 1997 ozone NAAQS and the 2008 ozone NAAQS.

[2] On March 11, 2015, the NCDENR requested that the EPA parallel process the approval of the submission.

VI. Final Action

The EPA is taking direct final action to approve the request from North Carolina for the EPA to relax the RVP applicable to gasoline introduced into commerce from June 1 to September 15 of each year in Mecklenburg and Gaston counties. Specifically, this action amends the applicable gasoline RVP standard from 7.8 psi to 9.0 psi provided at 40 CFR 80.27(a)(2) for Mecklenburg and Gaston counties.

The EPA is making this revision without prior proposal because the EPA views the revision as noncontroversial and anticipates no adverse comment. However, in the Proposed Rules section of this **Federal Register**, the EPA is publishing a separate document that will serve as the proposal to approve this revision to the gasoline RVP standard that applies in Mecklenburg and Gaston counties should adverse comments be filed. This rule will become effective October 16, 2015 without further notice unless the EPA receives adverse comments by September 16, 2015.

If the EPA receives adverse comments on the rule or any portion of the rule, the EPA will withdraw the direct final rule or the portion of the rule that received adverse comment. The EPA will publish a timely withdrawal in the **Federal Register** indicating which provisions will become effective and which provisions are being withdrawn. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on the subsequent final action. Any parties interested in commenting must do so at this time. If no such comments are received, the public is advised that this rule will become effective on October 16, 2015 and no further action will be taken on the proposed rule.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563. (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose any new information collection burden under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.,* and therefore is not subject to these requirements.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. The small entities subject to the requirements of this action are refiners, importers or blenders of gasoline that choose to produce or import low RVP gasoline for sale in North Carolina and gasoline distributers and retail stations in North Carolina. This action relaxes the federal RVP standard for gasoline sold in Mecklenburg and Gaston counties during the summertime ozone season (June 1 to September 15 of each year) to allow the RVP for gasoline sold in Mecklenburg and Gaston counties to rise from 7.8 psi to 9.0 psi. This rule does not impose any requirements or create impacts on small entities beyond those, if any, already required by or resulting from the CAA section 211(h) Volatility Control program. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This final rule 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. The action implements mandates specifically and explicitly set forth in CAA section 211(h) without the exercise of any policy discretion by the EPA.

E. 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.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This final rule affects only those refiners, importers or blenders of gasoline that choose to produce or import low RVP gasoline for sale in the Birmingham area and gasoline distributers and retail stations in the Birmingham area. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the 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 subject to Executive Order 13045 because it approves a state program.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

This action does not involve technical standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will *not* have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations because it does not affect the applicable ozone NAAQS which establish the level of protection provided to human health or the environment. This rule will relax the applicable volatility standard of gasoline during the summer, possibly resulting in slightly higher mobile source emissions. However, the state of North Carolina has demonstrated in its non-interference demonstration that this action will not interfere with maintenance of the ozone NAAQS in the Charlotte-Gastonia-Salisbury, North Carolina 2008 ozone area, or with any other applicable requirement of the CAA. Mecklenburg and Gaston counties are part of the Charlotte-Gastonia-Salisbury, North Carolina 2008 ozone area. Therefore, disproportionately high and adverse human health or environmental effects on minority or low-income populations are not an anticipated result. The results of this evaluation are contained in Section V. of this direct final rule. A copy of North Carolina's March 11, 2015 letter requesting that the EPA relax the gasoline RVP standard, including the technical analysis demonstrating that the less stringent gasoline RVP in the Mecklenburg and Gaston counties would not interfere with continued maintenance of the 2008 ozone NAAQS in the Charlotte-Gastonia-Salisbury, North Carolina ozone area, or with any other applicable CAA requirement, has been placed in the public docket for this action.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 16, 2015. Filing a petition for reconsideration by the Administrator of this direct final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel document of proposed rulemaking for this action published in the Proposed Rules section of this **Federal Register**, rather than file an immediate petition

for judicial review of this direct final rule, so that the EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. See CAA section 307(b)(2).

VIII. Legal Authority and Statutory Provisions

The statutory authority for this action is granted to the EPA by Sections 211(h) and 301(a) of the Clean Air Act, as amended; 42 U.S.C. 7545(h) and 7601(a).

List of Subjects in 40 CFR Part 80

Environmental protection, Administrative practice and procedures, Air pollution control, Fuel additives, Gasoline, Motor vehicle and motor vehicle engines, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

Dated: August 5, 2015.

Gina McCarthy,

Administrator.

For the reasons discussed in the preamble, the Environmental Protection Agency is amending 40 CFR part 80 as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7521, 7542, 7545, and 7601(a).

■ 2. In § 80.27(a)(2)(ii), the table is amended by:

■ a. Removing the entry for North Carolina and footnotes 6 and 7;

■ b. Redesignating footnote 8 as footnote 6;

■ c. Adding a new entry in alphabetical order for North Carolina and a new footnote 7.

The additions read as follows:

§ 80.27 Controls and prohibitions on gasoline volatility.

(a) * * *

(2) * * *

(ii) * * *

APPLICABLE STANDARDS[1] 1992 AND SUBSEQUENT YEARS

State	May	June	July	August	September
* * *	*	*	*	*	
North Carolina[7]	9.0	9.0	9.0	9.0	9.0
* * *	*	*	*	*	

[1] Standards are expressed in pounds per square inch (psi).

* * * * * * *

[7] The standard for Mecklenburg and Gaston Counties from June 1 until September 15 in 1992 through October 16, 2015 was 7.8 psi.

* * * * * * *

[FR Doc. 2015–20243 Filed 8–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0017; FRL–9930–16]

Lavandulyl Senecioate; 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 the arthropod pheromone, lavandulyl senecioate, in or on all raw agricultural commodities when applied or used in microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year in accordance with good agricultural practices. Suterra, LLC 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 lavandulyl senecioate.

DATES: This regulation is effective August 17, 2015. Objections and requests for hearings must be received on or before October 16, 2015, 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–2015–0017, 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, 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, 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–2015–0017 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 16, 2015. 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–2015–0017, 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 March 4, 2015 (80 FR 11611) (FRL–9922–68), 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 4F8292) by Suterra, LLC, 20950 NE Talus Place, Bend, OR 97701. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of lavandulyl senecioate in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient per acre per year. That document referenced a summary of the petition prepared by the petitioner Suterra, LLC, which is available in the docket via *http://www.regulations.gov.* No comments were received on the notice of filing.

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 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 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information 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.

A. Overview of Lavandulyl Senecioate

Lavandulyl senecioate (5-methyl-2-(1-methylethenyl)-4-hexenyl 3-methyl-2-butonate) is a technical grade synthetic arthropod pheromone. This arthropod pheromone is structurally similar to and mimics a naturally occurring pheromone produced by the female vine mealybug (*Planococcus ficus*) to attract males for mating. This pheromone is used to disrupt the normal mating cycle of the vine mealybug and has a non-toxic mode of action.

As an arthropod pheromone, lavandulyl senecioate is exempt from the requirement of a tolerance when used in retrievably sized polymeric matrix dispensers in or on all raw agricultural commodities when applied to growing crops only at a rate not to exceed 150 grams active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1124). The petitioner is requesting to apply this arthropod pheromone in an aqueous suspension of micro-bead/dispensers via normal spray equipment; therefore, the proposed new use of lavandulyl senecioate is not covered under the existing tolerance exemption listed in 40 CFR 180.1124. See the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Lavandulyl Senecioate'' (June 30, 2015), available in the docket for this action.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the petition to exempt residues of the arthropod pheromone, lavandulyl senecioate, from the requirement of a tolerance in or on all raw agricultural commodities when applied or used in microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year have been fulfilled. No significant toxicological effects were observed in any of the acute toxicity studies. Three mutagenicity studies submitted indicate that lavandulyl senecioate is not a mutagen. There are no known effects on endocrine systems via oral, dermal, or inhalation routes of exposure.

In the preamble to the final rule that exempted arthropod pheromones from the requirement of a tolerance when used in retrievably sized polymeric matrix dispensers, the Agency indicated that it did not have a toxicology

database for arthropod pheromones that addressed the potential risk of repeated, direct dietary exposure with sprayable formulations; therefore, at that time, the Agency limited the tolerance exemption to arthropod pheromones used in retrievably sized polymeric matrix dispensers with an annual rate limitation of 150 grams of active ingredient per acre. The Agency concluded that the limitations would not result in dietary exposure any greater than what may be found naturally as a result of heavy infestations of the pest arthropod. March 30, 1994 (59 FR 14757) (FRL–4761–9).

To address the subchronic and prenatal developmental toxicity data requirements for this exemption from the requirement of a tolerance for this arthropod pheromone, lavandulyl senecioate, the petitioner submitted scientific rationales that demonstrate that it is highly unlikely that there will be significant repeated exposure, including dietary exposure and exposure to female humans, to this pheromone when used as proposed based on the extremely low application rate, low emission rate, rapid volatilization after emission from the microbeads, and rapid biodegradation. Taking into account the petitioner's rationale, EPA has concluded that there is unlikely to be exposure that could result in subchronic and developmental effects and so has waived the requirements for subchronic and prenatal developmental testing.

For a full discussion of the data and rationale upon which EPA relied, and its human health risk assessment based on that data and rationale, please refer to the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Lavandulyl Senecioate'' (June 30, 2015). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

IV. Aggregate Exposures

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

In the preamble to the final rule, the Agency stated that limiting the exemption to applications of arthropod pheromones in retrievably sized dispensers would severely limit the possibility of direct dietary exposure. The Agency believed that restriction was necessary to protect public health due to a lack of data on repeat exposure but acknowledged that petitioners wanting to use other application methods or formulations could petition for an amendment by demonstrating that the new formulation did not increase the likely dietary exposure. For this tolerance exemption, based on the petitioner's submission concerning the proposed use, the Agency has determined that the proposed use (applying this arthropod pheromone in an aqueous suspension of microbead/dispensers via normal spray equipment with a limitation of 150 grams active ingredient/acre/year) will not result in detectable residues in or on all food commodities. That use is unlikely to result in significant dietary exposure to lavandulyl senecioate based on the extremely low application rate, low emission rate, rapid volatilization after emission from the microbeads, and rapid biodegradation (see document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Lavandulyl Senecioate'' (June 30, 2015), available in the docket for this action). No significant exposure via drinking water is expected based on the previous information for dietary exposure and the fact that the arthropod pheromone is not to be applied directly to water. However, should any dietary and/or drinking water exposure occur, minimal to no risk is expected for the general population, including infants and children, due to the low toxicity of lavandulyl senecioate as demonstrated in the data submitted and evaluated by the Agency, as fully explained in the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Lavandulyl Senecioate'' (June 30, 2015), available in the docket for this action.

B. Other Non-Occupational Exposure

Other non-occupational exposure (other than dietary) is not expected because the arthropod pheromone, lavandulyl senecioate, is not approved for residential uses.

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, 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 lavandulyl senecioate to share a common mechanism of toxicity with any other substances, and lavandulyl senecioate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that lavandulyl senecioate 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, 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 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 or no safety factor when reliable data are available to support a different additional or no safety factor.

As part of its qualitative assessment, EPA evaluated the available toxicity and exposure data on lavandulyl senecioate and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA considers the toxicity database to be complete and has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure. No hazard was identified based on the available studies, as fully explained in the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Lavandulyl

Senecioate'' (June 30, 2015), available in the docket for this action. Based upon its evaluation, EPA concludes that there are no threshold effects of concern to infants or children when lavandulyl senecioate is applied or used in microbeads/dispensers in or on all raw agricultural commodities at a rate not to exceed 150 grams active ingredient/acre/year. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

Based on the available data, EPA determines that there is a reasonable certainty that no harm will result from aggregate exposure to lavandulyl senecioate to the general U.S. population, including infants and children when applied to growing crops using microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year. EPA concludes that an exemption from the requirement of a tolerance for residues of lavandulyl senecioate in or on raw agricultural commodities when applied to growing crops using microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year is safe.

VII. Other Considerations

A. Analytical Enforcement Methodology

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

VIII. Conclusions

Therefore, an exemption is established for residues of the arthropod pheromone, lavandulyl senecioate, in or on all raw agricultural commodities when applied or used in microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year.

IX. 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) 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 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).

X. 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: July 31, 2015.

Robert McNally,

Director, Biopesticides and Pollution Prevention Division.

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 § 180.1332 to subpart D to read as follows:

§ 180.1332 Lavandulyl senecioate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the arthropod pheromone, lavandulyl senecioate (5-methyl-2-(1-methylethenyl)-4-hexenyl 3-methyl-2-butonate), in or on all raw agricultural commodities when applied or used in microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year in accordance with good agricultural practices.

[FR Doc. 2015–20257 Filed 8–14–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 120109034–2171–01]

RIN 0648–XE094

Fisheries of the Northeastern United States; Small-Mesh Multispecies Fishery; Adjustment to the Northern Red Hake Inseason Possession Limit

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

ACTION: Temporary rule; inseason adjustment.

SUMMARY: We announce the reduction of the commercial possession limit for northern red hake for the remainder of the 2015 fishing year. This action is

required to prevent the northern red hake total allowable landing limit from being exceeded. This announcement informs the public that the northern red hake possession limit is reduced.

DATES: Effective August 12, 2015 through April, 30, 2016.

FOR FURTHER INFORMATION CONTACT: Reid Lichwell, Fishery Management Specialist, 978–675–9112.

SUPPLEMENTARY INFORMATION: The small-mesh multispecies fishery is managed primarily through a series of exemptions from the Northeast Multispecies Fisheries Management Plan. Regulations governing the red hake fishery are found at 50 CFR part 648. The regulations describing the process to adjust inseason commercial possession limits of northern red hake are described in § 648.86(d)(4) and (5). These regulations require the Regional Administrator to reduce the northern red hake possession limit from 3,000 lb (1,361 kg) to 1,500 lb (680 kg) when landings have been projected to reach or exceed 45 percent of the total allowable landings (TAL). The northern red hake possession limit is required to be further reduced to 400 lb (181 kg) if landings are projected to reach or exceed 62.5 percent of the TAL, unless such a reduction would be expected to prevent the TAL from being reached. The setting of these inseason adjustment thresholds were established in the final rule implementing the small-mesh multispecies specifications for 2015–2017, published in the **Federal Register** on May 28, 2015 (80 FR 30379).

These measures were imposed because the annual catch limits (ACL) for northern red hake were exceeded for the 2012 and 2013 fishing years, and northern red hake was experiencing overfishing. To reduce the risk of continued overfishing on the stock and to better constrain catch to the ACL, we implemented this possession limit reduction trigger.

Based on commercial landings data reported through July 30, 2015, the northern red hake fishery is projected to reach 45 percent of the TAL on August 10, 2015. Based on this projection, reducing the commercial northern red hake possession limit to 1,500 lb (680 kg) is required to prevent the TAL from being exceeded. Upon the effective date of this action, no person may possess on board or land more than 1,500 lb (680 kg) of northern red hake, per trip for the remainder of the fishing year.

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

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

Dated: August 12, 2015.

Alan D. Risenhoover,

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

[FR Doc. 2015–20221 Filed 8–12–15; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 80, No. 158
Monday, August 17, 2015

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 950

RIN 3206–AM68

Solicitation of Federal Civilian and Uniformed Service Personnel for Contributions to Private Voluntary Organizations; Delay of Effective Date and Addition of Comment Period

AGENCY: Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing a proposed rule to delay the effective date that appeared in the final rule published in the **Federal Register** on April 17, 2014 titled ''Solicitation of Federal Civilian and Uniformed Service Personnel for Contributions to Private Voluntary Organizations'' to January 1, 2017. OPM is requesting comments on the proposed rule.

DATES: OPM must receive comments on or before September 16, 2015.

ADDRESSES: You may submit comments, identified by RIN number ''3206–AM68'', using the Federal eRulemaking Portal: *www.regulations.gov.* Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Mary Capule by telephone at (202) 606–2564; by FAX at (202) 606–5056; or by email at *cfc@opm.gov.*

SUPPLEMENTARY INFORMATION: OPM proposes to delay the effective date of the final rule entitled ''Solicitation of Federal Civilian and Uniformed Service Personnel for Contributions to Private Voluntary Organizations'' (FR Doc. 2014–08574, in the **Federal Register** of April 17, 2014 (79 FR 21581)), to January 1, 2017. The new effective date for the CFC regulations would ensure that the tools needed to put these reforms in place—including the pivotal online charity application and donor pledging systems—are thoroughly tested and fully operational before being made available to charities and donors.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2015–20238 Filed 8–14–15; 8:45 am]

BILLING CODE 6325–58–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Part 1605

Default Investment Fund Errors

AGENCY: Federal Retirement Thrift Investment Board

ACTION: Proposed rule with request for comments.

SUMMARY: The Federal Retirement Thrift Investment Board (Agency) proposes to amend its regulations to codify procedures for correcting certain default investment fund errors.

DATES: Submit comments on or before September 16, 2015.

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

- *Federal Rulemaking Portal: http://www.regulations.gov* at Docket ID number FRTIB–2015–0003. Follow the instructions for submitting comments.
- *Mail:* Office of General Counsel, Attn: James Petrick, Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002.
- *Hand Delivery/Courier:* The address for sending comments by hand delivery or courier is the same as that for submitting comments by mail.
- *Facsimile:* Comments may be submitted by facsimile at (202) 942–1676.

The most helpful comments explain the reason for any recommended change and include data, information, and the authority that supports the recommended change.

FOR FURTHER INFORMATION CONTACT: Austen Townsend at (202) 864–8647.

SUPPLEMENTARY INFORMATION: The Agency administers the Thrift Savings Plan (TSP), which was established by the Federal Employees' Retirement System Act of 1986 (FERSA), Public Law 99–335, 100 Stat. 514. The TSP provisions of FERSA are codified, as amended, largely at 5 U.S.C. 8351 and 8401–79. The TSP is a tax-deferred retirement savings plan for Federal civilian employees, members of the uniformed services, and spouse beneficiaries. The TSP is similar to cash or deferred arrangements established for private-sector employees under section 401(k) of the Internal Revenue Code (26 U.S.C. 401(k)).

On December 18, 2014, the President signed the Smart Savings Act (''the Act''), Public Law 113–255 (128 Stat. 2920). The Act directed the Agency to invest any sums available for investment in the TSP for which an election has not been made in an age-appropriate target date asset allocation investment fund. On July 13, 2015, the Agency published a proposed rule to change the TSP's default investment fund from the TSP's Government Securities Investment Fund to the age-appropriate TSP Lifecycle Fund (L Fund) for civilian employees. 80 FR 39974. This proposed regulation would update the TSP's existing error correction rules to address the correction of default investment fund errors caused by erroneous dates of birth.

Default Investment Fund Errors

Erroneous dates of birth can result from participant error, employing agency error, Agency error, or record-keeper error. A participant's date of birth is used to determine his or her age-appropriate L Fund. An erroneous date of birth might therefore cause a participant's TSP account to be invested in an L Fund that is different from the L Fund his or her account would have been invested in had the participant's correct date of birth been used. This proposed regulation provides that the Agency will pay breakage when an erroneous date of birth caused by Agency or record-keeper error results in default investment in the wrong L Fund.

In addition, the Agency will charge employing agencies breakage when an erroneous date of birth caused by employing agency error results in default investment in the wrong L Fund. To initiate a breakage calculation for an employee, the employing agency must notify the TSP that the participant is entitled to breakage. A date of birth change received from an employing agency will not trigger corrective action other than to update the date of birth.

Consistent with the existing error correction procedures at 5 CFR 1605.22 for contribution allocation and interfund transfer errors, the participant

must file a breakage claim within 30 days of either the date the TSP provides the participant with a notice reflecting the error or the date the TSP makes available on its Web site a participant statement reflecting the error, whichever is earlier.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation will affect Federal civilian employees and spouse beneficiaries who participate in the Thrift Savings Plan, which is a Federal defined contribution retirement savings plan created under the Federal Employees' Retirement System Act of 1986 (FERSA), Public Law 99–335, 100 Stat. 514, and which is administered by the Agency.

Paperwork Reduction Act

I certify that these regulations do not require additional reporting under the criteria of the Paperwork Reduction Act.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 602, 632, 653, 1501–1571, the effects of this regulation on state, local, and tribal governments and the private sector have been assessed. This regulation will not compel the expenditure in any one year of $100 million or more by state, local, and tribal governments, in the aggregate, or by the private sector. Therefore, a statement under section 1532 is not required.

List of Subjects in 5 CFR Part 1605

Government employees, Pensions, Retirement.

Gregory T. Long,

Executive Director, Federal Retirement Thrift Investment Board.

For the reasons stated in the preamble, the Agency proposes to amend 5 CFR chapter VI as follows:

PART 1605–CORRECTION OF ADMINISTRATIVE ERRORS

■ 1. The authority citation for part 1605 continues to read as follows:

Authority: 5 U.S.C. 8351, 8432(a), 8432(d), 8474(b)(5) and (c)(1). Subpart B also issued under section 1043(b) of Public Law 104–106, 110 Stat. 186 and § 7202(m)(2) of Public Law 101–508, 104 Stat. 1388.

■ 2. Amend § 1605.2 by revising the heading and paragraphs (b)(1)(i) and (c) to read as follows:

§ 1605.2 Calculating, posting, and charging breakage on late contributions and loan payments.

* * * * *

(b) * * *

(1) * * *

(i) Use the participant's contribution allocation on file for the ''as of'' date to determine how the funds would have been invested. If there is no contribution allocation on file, or one cannot be derived based on the investment of contributions, the TSP will consider the funds to have been invested in the default investment fund in effect for the participant on the ''as of'' date.

* * * * *

(c) *Posting contributions and loan payments.* Makeup and late contributions, late loan payments, and breakage, will be posted to the participant's account according to his or her contribution allocation on file for the posting date. If there is no contribution allocation on file for the posting date, they will be posted to the default investment fund in effect for the participant.

* * * * *

■ 3. Add § 1605.3 to read as follows:

§ 1605.3 Calculating, posting, and charging breakage on errors involving investment in the wrong fund.

(a) The TSP will calculate and post breakage on date of birth errors that result in default investment in the wrong L Fund, contribution allocation errors, and interfund transfer errors.

(b) The TSP will charge the employing agency for positive breakage on incorrect dates of birth caused by employing agency error that result in default investment in the wrong L Fund. A date of birth change received from an employing agency will not trigger corrective action other than to update the date of birth. To initiate a breakage calculation for an employee, the employing agency must notify the TSP that the participant is entitled to breakage.

■ 4. Amend § 1605.13 by revising paragraph (a)(3) to read as follows:

§ 1605.13 Back pay awards and other retroactive pay adjustments.

(a) * * *

(3) All contributions made under this paragraph (a) and associated breakage will be invested according to the participant's contribution allocation on the posting date. Breakage will be calculated using the share prices for the default investment fund in effect for the participant in accordance with § 1605.2 unless otherwise required by the employing agency or the court or other tribunal with jurisdiction over the back pay case.

* * * * *

■ 5. Amend § 1605.16, by re-designating the text of paragraph (a) as paragraph (a)(1), adding paragraph (a)(2), re-designating the text of paragraph (b) as paragraph (b)(1), and adding paragraphs (b)(2) and (b)(3) to read as follows:

§ 1605.16 Claims for correction of employing agency errors; time limitations.

(a) *Agency's discovery of error.* (1) Upon discovery of an error made within the past six months involving the correct or timely remittance of payments to the TSP (other than a retirement system misclassification error, as covered in paragraph (c) of this section), an employing agency must promptly correct the error on its own initiative. If the error was made more than six months before it was discovered, the agency may exercise sound discretion in deciding whether to correct it, but, in any event, the agency must act promptly in doing so.

(2) For errors involving incorrect dates of birth caused by employing agency error that result in default investment in the wrong L Fund, the employing agency must promptly notify the TSP that the participant is entitled to breakage if the error is discovered within 30 days of either the date the TSP provides the participant with a notice reflecting the error or the date the TSP makes available on its Web site a participant statement reflecting the error, whichever is earlier. If it is discovered after that time, the employing agency may use its sound discretion in deciding whether to pay breakage, but, in any event, must act promptly in doing so.

(b) *Participant's discovery of error.* (1) If an agency fails to discover an error of which a participant has knowledge involving the correct or timely remittance of a payment to the TSP (other than a retirement system misclassification error as covered by paragraph (c) of this section), the participant may file a claim with his or her employing agency to have the error corrected without a time limit. The agency must promptly correct any such error for which the participant files a claim within six months of its occurrence; if the participant files a claim to correct any such error after that time, the agency may do so at its sound discretion.

(2) For errors involving incorrect dates of birth that result in default investment in the wrong L Fund of which a participant or beneficiary has knowledge, he or she may file a claim for breakage with the employing agency

no later than 30 days after either the date the TSP provides the participant with a notice reflecting the error or the date the TSP makes available on its Web site a participant statement reflecting the error, whichever is earlier. The employing agency must promptly notify the TSP that the participant is entitled to breakage.

(3) If a participant or beneficiary fails to file a claim for breakage for errors involving incorrect dates of birth in a timely manner, the employing agency may nevertheless, in its sound discretion, pay breakage on any such error that is brought to its attention.

* * * * *

■ 6. Amend § 1605.22, by revising paragraphs (b)(2), (c)(2), and (c)(3) to read as follows:

§ 1605.22 Claims for correction of Board or TSP record keeper errors; time limitations.

* * * * *

(b) * * *

(1) * * *

(2) For errors involving an investment in the wrong fund caused by Board or TSP record keeper error, the Board or the TSP record keeper must promptly pay breakage if it is discovered within 30 days of the issuance of the most recent TSP participant (or loan) statement, transaction confirmation, or other notice that reflected the error, whichever is earlier. If it is discovered after that time, the Board or TSP record keeper may use its sound discretion in deciding whether to pay breakage, but, in any event, must act promptly in doing so.

(c) * * *

(1) * * *

(2) For errors involving an investment in the wrong fund of which a participant or beneficiary has knowledge, he or she may file a claim for breakage with the Board or TSP record keeper no later than 30 days after the TSP provides the participant with a transaction confirmation or other notice reflecting the error, or makes available on its Web site a participant statement reflecting the error, whichever is earlier. The Board or TSP record keeper must promptly pay breakage for such errors.

(3) If a participant or beneficiary fails to file a claim for breakage concerning an error involving an investment in the wrong fund in a timely manner, the Board or TSP record keeper may nevertheless, in its sound discretion, pay breakage for any such error that is brought to its attention.

* * * * *

■ 7. Amend § 1605.31 by revising paragraph (d) to read as follows:

§ 1605.31 Contributions missed as a result of military service.

* * * * *

(d) *Breakage.* The employee is entitled to breakage on agency contributions made under paragraph (c) of this section. The employee will elect to have the calculation based on either the contribution allocation(s) on file for the participant during the period of military service or the default investment fund in effect for the participant; the participant must make this election at the same time his or her makeup schedule is established pursuant to § 1605.11(c).

[FR Doc. 2015–20273 Filed 8–14–15; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2015–0046]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security DHS/CBP–001, Import Information System, System of Records, System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Homeland Security is giving concurrent notice for the newly established ''Department of Homeland Security/CBP–001, Import Information System, System of Records'' and this proposed rulemaking. In accordance with the Privacy Act of 1974, the Department of Homeland Security concurrently proposes to consolidate, update, and rename two current Department of Homeland Security systems of records titled, ''Department of Homeland Security/U.S. Customs and Border Protection, DHS/CBP–001 Automated Commercial Environment/International Trade Data System System of Records'' and ''Department of Homeland Security/U.S. Customs and Border Protection, DHS/CBP–015 Automated Commercial System System of Records'' as one new system of records. The consolidated system of records notice will be titled, ''Department of Homeland Security/U.S. Customs and Border Protection, DHS/CBP–001 Import Information System System of Records.'' This system of records will continue to collect and maintain records on all commercial goods imported into the United States, as well as information pertaining to the carrier, broker, importer, and other persons associated with the manifest, import, or commercial entry transactions for the goods. In this proposed rulemaking, the Department proposes to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: Comments must be received on or before September 16, 2015.

ADDRESSES: You may submit comments, identified by docket number DHS–2015–0046, by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: John Connors (202) 344–1610, CBP Privacy Officer, Office of the Commissioner, U.S. Customs and Border Protection, Washington, DC 20229. For privacy questions, please contact: Karen L. Neuman, (202) 343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS), U.S. Customs and Border Protection (CBP) proposes to consolidate, update, and rename as one system of records notice (SORN) the information currently contained in two DHS SORNs titled, ''DHS/CBP–001 Automated Commercial Environment/International Trade Data System (ACE/ITDS) System of Records'' (71 FR 3109, January 19, 2006) and ''DHS/CBP–015 Automated Commercial System (ACS) System of Records'' (73 FR 77759, December 19, 2008) . This new SORN, entitled ''DHS/CBP–001 Import Information System (IIS),'' will inform the public about changes to the

categories of individuals, categories of records, and routine uses contained in the consolidation of the former ACS and ACE/ITDS SORNs.

ACS, a decades old trade information database and information technology (IT) system, was deployed to track, control, and process all commercial goods imported into the United States. ACE, part of a multi-year modernization effort since 2001 to replace ACS, continues to be designed to manage CBP's import trade data and related transaction information. ACE/ITDS serves three sets of core stakeholders: The internal DHS/CBP users, Participating Government Agencies (PGA), and the trade community. ACE is the IT backbone for the ITDS, an interagency initiative formalized under the SAFE Port Act of 2006 to create a single window for the trade community and PGAs involved in importing and exporting. DHS/CBP has provided notice to the public and trade community that in the future, ACS, the IT system, will be fully phased out and replaced by ACE. As such, and to simplify the trade community's and the public's understanding of how trade information will be handled after ACE implementation, DHS/CBP is publishing this Import Information System (IIS) SORN to identify a single repository for import trade information. DHS/CBP is also publishing a combined ACE–ITDS/ACS Privacy Impact Assessment on its Web site (*http://www.dhs.gov/privacy*) to inform the public of the operation and inter-connectedness of the IT systems, ACS and ACE, and to assess the privacy impact of these systems using the fair information practice principles. This IIS system of records allows DHS/CBP to collect and maintain records on all commercial goods imported into the United States, along with related information about persons associated with those transactions, and manifest information.

As part of this consolidation and issuance of IIS, the category of individuals and category of records sections in the former ACS and ACE–ITDS have been merged to account for the data in both IT systems, as well as paper records related to the information in these systems. The category of individuals section is amended to remove reference to DHS/CBP employees and employees of other federal agencies for purposes of maintaining their user access accounts to the ACE–ITDS Portal, because these individuals are now covered under a DHS-wide SORN, ''DHS/ALL–004 General Information Technology Access Account Records System (GITAARS) (77 FR 70792, November 27, 2012). The category of records for IIS will also include notations and results of examinations and document review for cleared merchandise to clarify and better identify DHS and PGA-generated information related to the processing of the import entry transaction. Additionally, the category of records is being expanded to address the expansion of information DHS/CBP proposes to collect on its revised Importer ID Input Record (CBP Form 5106). DHS/CBP is adding required elements for the name (First, Middle, Last) and business contact information (job title and phone) of Senior Company Officers of the Importer; DHS/CBP is also adding optional data fields on the form for the Senior Officers to provide Social Security number (SSN) or Passport Number and Country of Issuance. These latter, optional data elements are to facilitate Importer screening and verification.

The authorities sections from the previous SORNs have been combined, reconciled to address duplication, and updated to account for expanded information collected about business associations as part of the ACE–ITDS Portal user account. The purpose section for IIS reflects an update to the combined purposes for ACS and ACE–ITDS and addresses DHS/CBP's broad use of its import trade transaction IT systems (ACS and ACE) to collect and manage records to track, control, and process all commercial goods imported into the United States.

Consistent with DHS's information-sharing mission, information stored in the DHS/CBP–001 Import Information System (IIS) may be shared with other DHS Components that have a need to know the information to carry out their national security, law enforcement, immigration, or other homeland security functions. In addition, information may be shared with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this SORN and as otherwise authorized under the Privacy Act.

Information in IIS may be shared for the same routine uses as were previously published in ACS and ACE–ITDS, and are now updated in this document:

- ACS's former Routine Use K is now reclassified as Routine Use G.
  - Routine Use G permits sharing of data under the following circumstances: ''To appropriate federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, license, or treaty where DHS determines that the information would assist in the enforcement of civil or criminal laws.''
- ACE–ITDS's former Routine Use 3 is now reclassified as Routine Use K.
  - Routine Use K permits sharing of data under the following circumstances: ''To a federal, state, local, tribal, territorial, foreign, or international agency, maintaining civil, criminal or other relevant enforcement information, or other pertinent information, which has requested information relevant to or necessary to the requesting agency's or the bureau's hiring or retention of an individual, or issuance of a security clearance, license, contract, grant, or other benefit.''

Additionally, DHS/CBP is adding another routine use to IIS, Routine Use R, to provide explicit coverage for the mandated release of Manifest Information as set forth in section 1431 of title 19, United States Code and implemented through title 19, Code of Federal Regulations, part 103:

- Routine Use R permits sharing of data under the following circumstances: ''To paid subscribers, in accordance with applicable regulations, for the purpose of providing access to manifest information as set forth in 19 U.S.C. 1431.''

DHS/CBP will not assert any exemptions with regard to information provided by or on behalf of an individual. However, this data may be shared with law enforcement and/or intelligence agencies pursuant to the routine uses identified in the IIS SORN and as otherwise authorized under the Privacy Act. The Privacy Act requires that DHS maintain an accounting of such disclosures. Disclosing the fact that a law enforcement and/or intelligence agency has sought particular records may interfere with or disclose techniques and procedures related to ongoing law enforcement investigations. As such, DHS is issuing a Notice of Proposed Rulemaking to exempt this system of records from certain provisions of the Privacy Act elsewhere in the **Federal Register**. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate personally identifiable information. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of

records'' is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and non-immigrant aliens.

The Privacy Act allows government agencies to exempt certain records from the access and amendment provisions. If an agency claims an exemption, however, it must issue a Notice of Proposed Rulemaking to make clear to the public the reasons why a particular exemption is claimed.

DHS is claiming exemptions from certain requirements of the Privacy Act for DHS/CBP–001 Import Information System System of Records.

No exemption shall be asserted with respect to information maintained in the system as it relates to data submitted by or on behalf of a person who travels to visit the United States, nor shall an exemption be asserted with respect to the resulting determination (authorized to travel, not authorized to travel, pending).

Some information in DHS/CBP–001 Import Information System System of Records relates to official DHS national security, law enforcement or intelligence activities. This system may contain records or information pertaining to the accounting of disclosures made from IIS to other law enforcement or intelligence agencies (Federal, State, local, foreign, international, or tribal) in accordance with the published routine uses. For the accounting of these disclosures only, in accordance with 5 U.S.C. 552a(j)(2) and (k)(2), DHS will claim the original exemptions for these records or information from subsection (c)(3), (e)(8), and (g) of the Privacy Act of 1974, as amended, as necessary and appropriate to protect such information. Moreover, DHS will add this exemption to Appendix C to 6 CFR part 5, DHS Systems of Records Exempt from the Privacy Act. Such exempt records or information may be law enforcement or national security investigation records, law enforcement activity and encounter records, or terrorist screening records.

DHS needs these exemptions in order to protect information relating to law enforcement investigations from disclosure to subjects of investigations and others who could interfere with investigatory and law enforcement activities. Specifically, the exemptions are required to: Preclude subjects of investigations from frustrating the investigative process; avoid disclosure of investigative techniques; protect the identities and physical safety of confidential informants and of law enforcement personnel; ensure DHS's and other federal agencies' ability to obtain information from third parties and other sources; protect the privacy of third parties; and safeguard sensitive information.

Nonetheless, DHS will examine each request on a case-by-case basis, and, after conferring with the appropriate component or agency, may waive applicable exemptions in appropriate circumstances and where it would not appear to interfere with or adversely affect the law enforcement or national security investigation.

Again, DHS will not assert any exemption with respect to information maintained in the system that is collected from a person and submitted by that person's air or vessel carrier, if that person, or his or her agent, seeks access or amendment of such information.

List of Subjects in 6 CFR Part 5

Freedom of information, Privacy.

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

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

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

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

■ 2. At the end of Appendix C to Part 5, add paragraph ''74'' to read as follows:

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

* * * * *

74. DHS/CBP–001, Import Information System (IIS). A portion of the following system of records is exempt from 5 U.S.C. 552a(c)(3), (e)(8), and (g)(1) pursuant to 5 U.S.C. 552a(j)(2), and from 5 U.S.C. 552a(c)(3) pursuant to 5 U.S.C. 552a(k)(2). Further, no exemption shall be asserted with respect to information maintained in the system as it relates to data submitted by or on behalf of a person who travels to visit the United States and crosses the border, nor shall an exemption be asserted with respect to the resulting determination (approval or denial). After conferring with the appropriate component or agency, DHS may waive applicable exemptions in appropriate circumstances and where it would not appear to interfere with or adversely affect the law enforcement purposes of the systems from which the information is recompiled or in which it is contained. Exemptions from the above particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, when information in this system of records is may impede a law enforcement, intelligence activities and national security investigation:

(a) From subsection (c)(3) (Accounting for Disclosure) because making available to a record subject the accounting of disclosures from records concerning him or her would specifically reveal any investigative interest in the individual. Revealing this information could reasonably be expected to compromise ongoing efforts to investigate a violation of U.S. law, including investigations of a known or suspected terrorist, by notifying the record subject that he or she is under investigation. This information could also permit the record subject to take measures to impede the investigation, *e.g.,* destroy evidence, intimidate potential witnesses, or flee the area to avoid or impede the investigation.

(b) From subsection (e)(8) (Notice on Individuals) because to require individual notice of disclosure of information due to compulsory legal process would pose an impossible administrative burden on DHS and other agencies and could alert the subjects of counterterrorism or law enforcement investigations to the fact of those investigations when not previously known.

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

Dated: July 31, 2015.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2015–19726 Filed 8–14–15; 8:45 am]

BILLING CODE 9111–14–P

NUCLEAR REGULATORY COMMISION

10 CFR Chapter I

[NRC–2015–0176]

Abnormal Occurrence Reports

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed revision to policy statement; request for comments.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing revisions to its policy statement on reporting abnormal occurrences (AO) to Congress. The proposed revisions would clarify and restructure the criteria used by the NRC and Agreement States for determining whether to consider an incident or event as an AO. The proposed revisions to the policy statement would ensure consistency with current NRC guidance and

regulations. The NRC is requesting public comments on the proposed revision to the policy statement at this time.

DATES: Submit comments by November 16, 2015. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0176. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, 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: Luis A. Benevides, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–2457; email: *Luis.Benevides@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0176 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 Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0176.
- *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 ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *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.

B. Submitting Comments

Please include Docket ID NRC–2015–0176 in the subject line of your comment submission.

The NRC cautions you not to include identifying or contact information 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. 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

Section 208 of the Energy Reorganization Act of 1974, as amended (Pub. L. 93–438), defines an AO as an unscheduled incident or event that the NRC determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Pub. L. 104–66) requires that AOs be reported to Congress annually. As required by Section 208, the discussion for each event includes the date and place, the nature and probable consequences, the cause or causes, and the action taken to prevent recurrence. The Commission must also widely disseminate the AO report to the public within 15 days of publishing the AO report to Congress.

Abnormal Occurrence Reporting

The Commission has developed the AO policy statement to comply with Section 208 of the Energy Reorganization Act of 1974, as amended. The intent of the act is to keep Congress and the public informed of unscheduled incidents or events that the Commission considers significant from the standpoint of public health and safety. The policy reflects a range of health and safety concerns and applies to incidents and events involving a single individual, as well as those having an overall impact on the general public. The AO criteria use a high reporting threshold so that only those events considered significant from the standpoint of public health and safety are reported to Congress.

Applicability

Implementation of Section 208 of the Energy Reorganization Act of 1974, as amended, ''Abnormal Occurrence Reports,'' involves the conduct of Commission business and does not impose requirements on licensees or certified facilities. The reports cover certain unscheduled incidents or events related to the manufacture, construction, or operation of a facility or conduct of an activity subject to the requirements of parts 20, 30 through 37, 39, 40, 50, 61, 70, 71, 72, or 76 in chapter I of Title 10 of the *Code of Federal Regulations* (10 CFR).

Agreement States provide information to the NRC on incidents and events involving applicable nuclear materials in their States. Agreement States are those States that have entered into formal agreements with the NRC, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (AEA) (Pub. L. 83–703), to regulate certain quantities of AEA material at facilities located within their borders. Events reported by Agreement States that reach the threshold for reporting as AOs are also published in the ''Report to Congress on Abnormal Occurrences.''

Proposed Revisions

The NRC is proposing revisions to the AO criteria to clarify the criteria for determining events that are significant from the standpoint of public health and safety and should therefore be considered AOs. The proposed revisions would also make the criteria consistent with NUREG–1614, Volume 6, ''U.S. Nuclear Regulatory Commission's Strategic Plan for Fiscal Years 2014–2018,'' issued August 2014 (ADAMS Accession No. ML14246A439), and new NRC requirements in 10 CFR part 37, ''Physical protection of category 1 and category 2 quantities of radioactive material.'' Further, the NRC proposes to revise the AO criteria to separate ''Other Events of Interest'' from the AO criteria to clearly delineate that events considered ''Other Events of Interest'' are not AOs, but do represent significant

events that the Commission deems appropriate to report to Congress. Finally, restructuring and minor editorial changes are proposed to some sections for clarity.

The NRC is requesting public comments on the proposed revision to the policy statement at this time. The NRC is specifically seeking public comments on screening all reports for exposures to embryo/fetus or nursing child as an AO under Criteria l.A.2, unintended radiation exposure, versus screening reports required by 10 CFR 35.3047 for exposures to embryo/fetus or nursing child resulting from treatment to a patient as an AO under Criteria III.C, ''Events involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.''

The entire text of the proposed revision of the policy statement is available as an attachment to this document.

Licensee Reports

The proposed changes to the general policy statement would not change the reporting requirements for NRC licensees in Commission regulations, license conditions, or technical specifications. The NRC licensees will continue to submit required reports on a wide range of events, including instrument malfunctions and deviations from normal operating procedures that may not be significant from the standpoint of the public health and safety but provide data useful to the Commission in monitoring operating trends of licensed facilities and in comparing the actual performance of these facilities with their design and/or licensing basis.

III. Paperwork Reduction Act

This policy statement does not contain information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Public Protection Notification

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

Dated at Rockville, Maryland, this 10th day of August, 2015.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

Attachment—Abnormal Occurrence Statement of Policy

The Commission will apply the following policy in determining whether an incident or event at a facility or involving an activity that is licensed or otherwise regulated by the Commission or an Agreement State is an abnormal occurrence (AO).[1]

An incident or event is considered an AO if it involves a major reduction in the protection of public health or safety. The incident or event has a moderate or severe impact on public health or safety and could include, but need not be limited to, the following:

(1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission or Agreement States;

(2) major degradation of essential safety-related equipment;

(3) major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission or Agreement States; or

(4) substantiated case of actual loss, theft, or diversion of risk significant radioactive material licensed by or otherwise regulated by the Commission or Agreement States.

The criteria for determining whether to consider an incident or event for reporting as an AO are set forth in Appendix A of this policy statement.

Commission Dissemination of Abnormal Occurrence Information

The Commission widely disseminates the AO reports to the public. The Commission will submit an annual report to Congress on AOs that occur at or are associated with any facility or activity that is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. This report gives the date, place, nature, and probable consequences of each AO; the cause or causes of each AO; and any action taken to prevent recurrence.

Appendix A: Abnormal Occurrence Criteria

An accident or event is considered an abnormal occurrence (AO) if it involves a major reduction in the degree of protection of public health or safety. This type of incident or event has a moderate or severe impact on public health or safety and could include, but need not be limited to, the following:

(1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission or Agreement States;

(2) major degradation of essential safety-related equipment;

(3) major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission or Agreement States; or

(4) substantiated case of actual loss, theft, or diversion of risk-significant radioactive material licensed by or otherwise regulated by the Commission or Agreement States.

Abnormal Occurrence Criteria

The following presents the criteria, by types of events, used to determine which events will be considered for reporting as AOs.

I. All Licensees[2]

A. Human Exposure to Radiation From Licensed Material

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in:

(a) An annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more;

(b) an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 mSv (250 rem) or more;

(c) an annual dose equivalent to the lens of the eye of 1 Sv (100 rem) or more;

(d) an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more;

(e) a committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or

(f) an annual shallow dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by an independent physician[3] deemed qualified by the NRC or Agreement State.

[1] Events reported to the U.S. Nuclear Regulatory Commission (NRC) by Agreement States that reach the threshold for reporting as AOs will be reported as such by the Commission.

[2] Medical patients are excluded from consideration under this criterion and these criteria do not apply to medical events defined in § 35.3045 of Title 10 of the *Code of Federal Regulations* (10 CFR), which are considered in AO Criteria III.C, ''Events involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.''

[3] Independent physician is defined to be a physician not on the licensee's staff and who was not involved in the care of the patient involved.

B. Discharge or Dispersal of Radioactive Material From Its Intended Place of Confinement

The release of radioactive material to an unrestricted area in concentrations that, if averaged over a period of 24 hours, exceeds 5,000 times the values specified in Table 2 of appendix B, ''Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,'' to 10 CFR part 20, ''Standards for protection against radiation,'' unless the licensee has demonstrated compliance with 10 CFR 20.1301, ''Dose limits for individual members of the public,'' using 10 CFR 20.1302(b)(1) or 10 CFR 20.1302(b)(2)(ii). This criterion does not apply to transportation events.

C. Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach[4][5][6]

1. Any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in appendix A of 10 CFR part 37, ''Physical protection of category 1 and category 2 quantities of radioactive material.'' Excluded from reporting under this criterion are those events involving sources that are lost or abandoned under the following conditions: Sources that have been lost and for which a reasonable attempt at recovery has been made without success or irretrievable well logging sources as defined in 10 CFR 39.2, ''Definitions.'' These sources are only excluded if there is reasonable assurance that the doses from these sources have not exceeded and will not exceed the reporting thresholds specified in AO Criteria I.A.1 and I.A.2 and the agency has determined that the risk of theft or diversion is acceptably low.

2. An act that results in radiological sabotage as defined in 10 CFR 73.2, ''Definitions.''

3. Any substantiated[7] case of actual theft, diversion, or loss of a formula quantity of special nuclear material[8] or an inventory discrepancy of a formula quantity of special nuclear material that is judged to be caused by theft or diversion.

4. Any substantial breakdown[9] of physical security, cyber security, or material control and accountability programs that significantly weakens the protection against loss, theft, diversion, or sabotage.

5. Any significant unauthorized disclosures (loss, theft, and/or deliberate) of classified information that harms national security or safeguards information that threatens public health and safety.

D. Initiation of High-Level NRC Team Inspection[10]

II. Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of license technical specification (TS) (10 CFR 50.36(c)).

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR part 100, ''Reactor Site Criteria,'' or five times the dose limits of General Design Criteria (GDC) 19 in appendix A, ''General Design Criteria for Nuclear Power Plants,'' to 10 CFR part 50, ''Domestic licensing of production and utilization facilities,'' could occur from a postulated transient or accident (*e.g.,* loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy

1. Discovery of a major condition not specifically considered in the safety analysis report or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR part 100 or five times the dose limits of GDC 19 in appendix A to 10 CFR part 50, could occur from a postulated transient or accident (*e.g.,* loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any Operating Reactor Events or Conditions Evaluated by the NRC Reactor Oversight Process (ROP) To Be the Result of or Associated With Licensee Performance Issues of High Safety Significance[11]

D. Any Operating Reactor Events or Conditions Evaluated by the NRC Accident Sequence Precursor (ASP) Program To Have a Conditional Core Damage Probability (CCDP) or Change in Core Damage Probability (ΔCDP) of Greater Than or Equal to 1×10^{-3}[12]

E. Any Operating Reactor Plants That Are Determined To Have Overall Unacceptable Performance or Are in a Shutdown Condition as a Result of Significant Performance Problems and/or Operational Event(s)[13]

III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events

A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal

1. An accidental criticality.

2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.

3. A serious safety-significant deficiency in management or procedural controls.

4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities

[4] Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Executive Order 13526, as amended (''Classified National Security Information'' (75 FR 707), or any predecessor or successor order to require protection against unauthorized disclosures. Any classified details about these incidents would be available to the Congress, upon request, under appropriate security arrangements.

[5] Information pertaining to certain incidents may be Safeguards Information as defined in 10 CFR 73.2 because of safety and security implications. The AO report would withhold specific safeguards information in accordance with Section 147 of the Atomic Energy Act of 1954, as amended. Any safeguards details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

[6] Reporting lost or stolen material is based on the activity of the source at the time the radioactive material was known to be lost or stolen. If, by the time the AO report is due to Congress, the radioactive material has decayed to below the thresholds listed in appendix A of 10 CFR part 37, the report will clarify that the radioactive material has decayed below the thresholds.

[7] ''Substantiated'' means a situation in which there is an indication of loss, theft, or unlawful diversion, such as: An allegation of diversion, report of lost or stolen material, or other indication of loss of material control or accountability that cannot be refuted following an investigation; and requires further action on the part of the agency or other proper authorities.

[8] Formula quantity of special nuclear material is defined in 10 CFR 70.4, ''Definitions.''

[9] A substantial breakdown is defined as a red finding under the Reactor Oversight Process (ROP) in the physical security inspection program or any plant or facility determined to have overall unacceptable performance.

[10] This item addresses initiation of any incident investigation teams, as described in NRC Management Directive (MD) 8.3, ''NRC Incident Investigation Program'' (*see http://www.internal.nrc.gov/policy/directives/toc/md8.3.htm*), or initiation of any accident review groups, as described in MD 8.9, ''Accident Investigation'' (*see http://www.internal.nrc.gov/policy/directives/toc/md8.9.htm*).

[11] The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC MD 8.13, ''Reactor Oversight Process'' (*see http://www.internal.nrc.gov/policy/directives/toc/md8.13.htm*), green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered AOs.

[12] Results from the NRC ASP program are used to monitor agency performance against the agency's strategic safety goal (*e.g.,* ensure the safe use of radioactive materials) and objectives (*e.g.,* prevent and mitigate accidents and ensure radiation safety). A precursor event with a CCDP or ΔCDP of greater than or equal to 1×10^{-3} is used as a performance indicator for the strategic safety goal by determining that there have been no significant precursors of a nuclear reactor accident and that there have been no more than one significant adverse trend in industry safety performance.

[13] Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter (IMC) 0305, ''Operating Reactor Assessment Program'' (*see http://pbadupws.nrc.gov/docs/ML1508/ML15089A315.pdf*), or under the NRC IMC 0350, ''Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns'' (see *http://pbadupws.nrc.gov/docs/ML0634/ML063400076.pdf*). This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

(generic incidents) that raise a major safety concern.

B. Fuel Cycle Facilities [14]

1. Absence or failure of all safety controls (engineered and human) such that conditions were present for the occurrence of a high-consequence event involving an NRC-regulated hazard (radiological or chemical).[15]

2. An NRC-ordered safety-related or security-related immediate remedial action.

C. Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects [16]

1. A medical event, as defined in 10 CFR 35.3045, which results in a dose that:

(a) Is equal to or greater than 1 Gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or

(b) exceeds, by 10 Gy (1,000 rad), the expected dose to any other organ or tissue from the administration defined in the written directive; and

2. A medical event, as defined in 10 CFR 35.3045, which involves:

(a) A dose or dosage that is at least 50 percent greater than that prescribed, or

(b) a prescribed dose or dosage that

(i) uses the wrong radiopharmaceutical or unsealed byproduct material; or

(ii) is delivered by the wrong route of administration; or

(iii) is delivered to the wrong treatment site; or

(iv) is delivered by the wrong treatment mode; or

(v) is from a leaking source or sources; or

(vi) is delivered to the wrong individual or human research subject.

Appendix B: Other Events of Interest

This appendix discusses other events of interest that do not meet the AO criteria in Appendix A. The Commission may determine that events, other than AOs, may be of interest to Congress and the public and should be included in an appendix to the AO report as ''Other Events of Interest.'' Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

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BILLING CODE 7590–01–P

[14] Criterion III.A also applies to Fuel Cycle Facilities.

[15] High-consequence events for facilities licensed under 10 CFR part 70 are those that could seriously harm the worker or a member of the public in accordance with 10 CFR 70.61. The integrated safety analysis (ISA) conducted and maintained by the licensee or applicant of 10 CFR part 70 fuel cycle facilities identifies such hazards and the safety controls (10 CFR 70.62(c)) applied to meet the performance requirements in accordance with 10 CFR 70.61(b) through (d). Fuel cycle facilities licensed under 10 CFR part 40 or certified under 10 CFR part 76 have licensing basis documents that describe facility specific hazards, consequences, and those controls utilized to prevent or mitigate the consequences of such accidents. For these facilities, a high-consequence event would be a release that has the potential to cause acute radiological or chemical exposures to a worker or a member of the public similar to that defined in NUREG–1520, Revision 2, Appendix A to Chapter 3, Section A.2, under ''Consequence Category 3 (High Consequences)'' (see *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1520/*).

[16] Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2014–0370; Airspace Docket No. 14–ASO–2]

RIN 2120–AA66

Proposed Redesignation and Expansion of Restricted Area R–4403; Gainesville, MS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: This SNPRM amends the notice of proposed rulemaking (NPRM) published in the **Federal Register** on July 10, 2014, proposing to redesignate and expand restricted area R–4403, Gainesville, MS, by changing the parameters of some restricted area subareas. The changes would include expanding the time of designation, modifying some restricted area lateral and vertical boundaries, and eliminating the proposed air-to-ground munitions delivery in some parts of the restricted area complex.

DATES: Comments must be received on or before October 1, 2015.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; telephone: (202) 366–9826. You must identify FAA Docket No. FAA–2014–0370 and Airspace Docket No. 14–ASO–2, at the beginning of your comments. You may also submit comments through the Internet at *www.regulations.gov.* Comments on environmental and land use aspects to should be directed to: Mr. David Lorance, P.E., Center Environmental Officer, Center Operations Directorate, National Aeronautics and Space Administration (NASA) Stennis Space Center, Roy S. Estess Building 1100, Mail Code RA02, Stennis Space Center, MS 39529–6000.

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

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 the 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 restructure the restricted airspace at the Stennis Space Center, MS, to enhance aviation safety and accommodate essential NASA and Naval Special Warfare Command (NSWC) requirements.

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 (FAA Docket No. FAA–2014–0370 and Airspace Docket No. 14–ASO–2) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2014–0370 and Airspace Docket No. 14–ASO–2.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. 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 *www.regulations.gov.*

You may review the public docket containing the proposal, any comments received and any final disposition in person at the Dockets Office (see **ADDRESSES** section for 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 office of the Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave., College Park, GA 30337.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

On July 10, 2014, the FAA published in the **Federal Register** an NPRM proposing to redesignate and expand restricted area R–4403, Gainesville, MS, to support missions of the National Aeronautics and Space Administration (NASA) and the Naval Special Warfare Command (NSWC) (79 FR 39344). Eight comments were received; two commenters supported the proposal, four commenters posed limited concerns, and the remaining two commenters objected to the proposal.

Subsequent to publication, both NASA and NSWC revised their airspace proposal by changing certain restricted area boundaries, eliminating some proposed activities and increasing the proposed times of use of the airspace. The changes are described in the next section, below.

Since these changes to the proposal are significant, the FAA has determined it is necessary to reopen the comment period to provide additional opportunity for public comment. The FAA will dispose of all the comments to the NPRM and SNPRM when it issues its final determination on the proposal.

Differences From NPRM

The southern boundary of R–4403B and R–4403C is shifted slightly to the north to address a comment that the restricted areas were too close to Interstate I–10, which is used by some pilots as a visual flight reference.

The NPRM proposed to establish R–4403C, extending from the surface up to but not including 6,000 feet MSL; and to establish R–4403D, with the same lateral boundaries as R–4403C, and extending above R–4403C from 6,000 feet MSL up to 10,000 feet MSL. This SNPRM proposes to combine R–4403C and R–4403D into a single restricted area extending from the surface up to 10,000 feet MSL. This combined area would be designated R–4403C and the formerly proposed designation ''R–4403D'' would not be used.

The NPRM proposed the time of designation for restricted areas R–4403C, D, E and F as ''Intermittent, 1800 to 2400 local time, as activated by NOTAM at least 24 hours in advance; other times by NOTAM with air traffic control (ATC) approval.'' The SNPRM would revise the time of designation for R–4403C, E and F to ''Intermittent, 2000 to 0500 local time, as activated by NOTAM at least 24 hours in advance; and 1800 to 2000 local time, November 1 to March 1, as activated by NOTAM at least 24 hours in advance, not to exceed 20 days per year.'' The new times would expand the basic time frame during which the restricted areas could be activated from six hours per day to nine hours per day. Further, it would add a provision allowing for additional activation during the hours 1800 to 2000 local time between November 1 and March 1. However, use of the 1800 to 2000 time frame between November 1 and March 1 would be limited to a maximum of 20 days per year. The provision in the NPRM allowing for activation of R–4403C, E and F at ''other times by NOTAM with ATC approval'' is removed from consideration in this proposal.

The NPRM proposed the use of R–4403E and F for delivery of air-to-ground munitions at a ground target by aircraft, including AC–130 gunships and armed helicopters. The NSWC determined that the area is too small to contain the weapons safety footprint, so R–4403E and F would only be used to contain air-to-ground firing of non-eye-safe lasers. Ground forces would use lasers that are eye-safe in R–4403E and F to signal military aircraft operating overhead.

The southeastern-most point of the R–4403E boundary (where it intersects the Stennis International Airport Class D airspace boundary (at lat. 30°20′22″ N., long. 89°31′43″ W.) would be shifted northward by approximately 2.5 NM to intersect the Class D airspace area at lat. 30°22′35″ N., long. 89°32′06″ W. The airspace south of the new line would become a part of R–4403C.

The Proposal

The FAA is proposing an amendment to 14 CFR part 73 to remove restricted area R–4403, Gainesville, MS, and redesignate and expand the airspace to consist of five subareas: R–4403A, B, C, E and F, Stennis Space Center, MS. The FAA is proposing this action at the request of NASA and the NSWC to confine activities that potentially present hazards to nonparticipating aircraft. The existing airspace is too small to fully contain NASA activities and the proposed expansion would also enable NSWC to conduct realistic Special Operations Force training.

R–4403A and B would continue be used for NASA activities, such as rocket engine testing and untethered space vehicle propulsion system testing. The NSWC would use the proposed R–4403C, E and F for integrated Special Operations Forces training. The proposed restricted areas are described below.

R–4403A would be used by NASA to test rocket engine technology. It would consist of that airspace within a 2.5 NM radius of lat. 30°21′51″ N., long. 89°35′39″ W., centered on the rocket engine test complex. R–4403A would extend from the ground to 12,000 feet MSL. It would replace R–4403 with an expanded area to more fully contain rocket engine testing hazards. This area remains as proposed in the NPRM.

R–4403B would be used by NASA for untethered autonomous space vehicle testing. The area would extend upward from the ground to 6,000 feet MSL. These vehicles are utilized to explore planets and asteroids. Testing of these vehicles involves potential hazards since failure of the vehicle, its propulsion system or propellant tanks can result in explosion of the vehicle. The propensity for this to occur is greater with these vehicles than with a standard aircraft because of the extremely volatile nature of the propellants and the poor aerodynamic characteristics of the vehicle during earth-based operation. Proposed R–4403B is designed to contain the flight profiles of these vehicles as well as any potential hazards to nonparticipating aircraft. Except for the slight adjustment of the southern boundary, as described

above, this area remains as proposed in the NPRM.

R–4403C would be used for Special Operations Forces Integration Training. The NPRM proposed R–4403C to extend from the ground to 6,000 feet MSL. This SNPRM would expand R–4403C to extend from the ground to 10,000 feet MSL, incorporating the airspace from 6,000 feet MSL to 10,000 feet MSL, which was formerly proposed as R–4403D. The designation ''R–4403D'' will no longer be used. R–4403C would contain air-to-ground live-fire training for AC–130 gunships, armed helicopters and tilt-rotor (CV–22) aircraft and surface-to-surface weapons firing. R–4403C would contain two impact areas for air-to-ground munitions employment (up to 105mm), and air-to-ground non-eye-safe laser firing. Ground forces would use lasers that are eye-safe to signal military aircraft operating overhead. Anticipated use of R–4403C is 100–120 days per year.

R–4403D designation is removed from the proposal as described above.

R–4403E would also be used for Special Operations Forces Integration Training. It would extend upward from the ground to 10,000 feet MSL. It would contain a ground target to be used only for air-to-ground firing of non-eye safe lasers. The proposal in the NPRM to use this area for air-to-ground munitions delivery is eliminated. Ground forces would also use lasers that are eye-safe to signal military aircraft operating overhead.

R–4403F would extend upward from 4,000 feet MSL to 10,000 feet MSL. R–4403F would wrap around the northeast corner of R–4403E and would be used in conjunction with R–4403E.

R–4403E and F would always be activated together for AC–130 air-to-ground firing of non-eye-safe lasers. The two areas could be activated separately from R–4403C, but typically would be used in conjunction with R–4403C.

The proposed time of designation for R–4403A and R–4403B is ''Intermittent, 1000 to 0300 local time, as activated by NOTAM at least 24 hours in advance.'' This time frame is the same as proposed in the NPRM. The proposed time of designation for R–4403C, E and F is ''Intermittent, 2000 to 0500 local time, as activated by NOTAM at least 24 hours in advance; and 1800 to 2000 local time, November 1 to March 1 (not to exceed 20 days per year).'' The times for R–4403C, E and F are changed from those in the NPRM as explained in the ''Differences from NPRM'' section, above.

Note: The term ''Intermittent'' is used to indicate occasional, irregular, or changeable use periods.

During periods when the restricted areas are not needed by the using agencies, the airspace would be returned to the controlling agency for access by other airspace users.

A revised color chart depicting the proposed restricted areas will be posted on the *www.regulations.gov* Web site (search Docket No. FAA–2014–0370).

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. Therefore, this proposed regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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, will 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 1050.1E, ''Environmental Impacts: Policies and Procedures,'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Proposed Amendment

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

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 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.

§ 73.44 [Amended]

■ 2. Section 73.44 is amended as follows:

R–4403 Gainesville, MS [Removed]

R–4403A Stennis Space Center, MS [New]

Boundaries. Within a 2.5-NM radius centered at lat. 30°21′51″ N., long. 89°35′39″ W.

Designated altitudes. Surface to 12,000 feet MSL.

Time of designation. Intermittent, 1000 to 0300 local time, as activated by NOTAM at least 24 hours in advance.

Controlling agency. FAA, Houston ARTCC.

Using agency. NASA, Director, Stennis Space Center, Bay St. Louis, MS.

R–4403B Stennis Space Center, MS [New]

Boundaries. Beginning at lat. 30°29′37″ N., long. 89°35′16″ W.;
to lat. 30°29′37″ N., long. 89°32′33″ W.;
thence clockwise along a 0.85-NM arc centered
at lat. 30°28′46″ N., long. 89°32′33″ W.;
to lat. 30°28′46″ N., long. 89°31′34″ W.;
to lat. 30°26′25″ N., long. 89°31′34″ W.;
to lat. 30°24′02″ N., long. 89°31′34″ W.;
thence counterclockwise along a 4.2-NM arc centered
at lat. 30°22′04″ N., long. 89°27′17″ W.;
to lat. 30°20′28″ N., long. 89°31′46″ W.;
to lat. 30°19′19″ N., long. 89°35′32″ W.;
to lat. 30°18′23″ N., long. 89°40′17″ W.;
to lat. 30°21′08″ N., long. 89°42′25″ W.;
to lat. 30°22′22″ N., long. 89°42′58″ W.;
to lat. 30°23′44″ N., long. 89°42′43″ W.;
to lat. 30°26′40″ N., long. 89°40′51″ W.;
thence counterclockwise along a 3-NM arc centered
at lat. 30°29′15″ N., long. 89°39′04″ W.;
to lat. 30°27′08″ N., long. 89°36′37″ W.;
to lat. 30°27′58″ N., long. 89°35′27″ W.;
to lat. 30°28′47″ N., long. 89°35′27″ W.;
to the point of beginning.

Designated altitudes. Surface to 6,000 feet MSL.

Time of designation. Intermittent, 1000 to 0300 local time, as activated by NOTAM at least 24 hours in advance.

Controlling agency. FAA, Houston ARTCC.

Using agency. NASA, Director, Stennis Space Center, Bay St. Louis, MS.

R–4403C Stennis Space Center, MS [New]

Boundaries. Beginning at lat. 30°27′58″ N., long. 89°35′27″ W.;
to lat. 30°22′35″ N., long. 89°35′27″ W.;
to lat. 30°22′35″ N., long. 89°32′06″ W.;
thence counterclockwise along a 4.2-NM arc centered
at lat. 30°22′04″ N., long. 89°27′17″ W.;
to lat. 30°20′28″ N., long. 89°31′46″ W.;
to lat. 30°19′19″ N., long. 89°35′32″ W.;
to lat. 30°18′23″ N., long. 89°40′17″ W.;
to lat. 30°21′08″ N., long. 89°42′25″ W.;
to lat. 30°22′22″ N., long. 89°42′58″ W.;
to lat. 30°23′44″ N., long. 89°42′43″ W.;
to lat. 30°26′40″ N., long. 89°40′51″ W.;
thence counterclockwise along a 3-NM arc centered
at lat. 30°29′15″ N., long. 89°39′04″ W.;
to lat. 30°27′08″ N., long. 89°36′37″ W.;
to the point of beginning.

Designated altitudes. Surface to 10,000 feet MSL.

Time of designation. Intermittent, 2000 to 0500 local time, as activated by NOTAM at least 24 hours in advance; and 1800 to 2000 local time, November 1 to March 1, as

activated by NOTAM at least 24 hours in advance, not to exceed 20 days per year.

Controlling agency. FAA, Houston ARTCC.

Using agency. U.S. Navy, Commander, Naval Special Warfare Command, Naval Special Warfare N31 Branch, Stennis Space Center, Bay St. Louis, MS.

R–4403E Stennis Space Center, MS [New]

Boundaries. Beginning at lat. 30°29′37″ N., long. 89°35′16″ W.;

to lat. 30°29′37″ N., long. 89°32′33″ W.;

thence clockwise along a 0.85-M arc centered

at lat. 30°28′46″ N., long. 89°32′33″ W.;

to lat. 30°28′46″ N., long. 89°31′34″ W.;

to lat. 30°26′25″ N., long. 89°31′34″ W.;

to lat. 30°24′02″ N., long. 89°31′34″ W.;

thence counterclockwise along a 4.2-NM arc centered

at lat. 30°22′04″ N., long. 89°27′17″ W.;

to lat. 30°22′35″ N., long. 89°32′06″ W.;

to lat. 30°22′35″ N., long. 89°35′27″ W.;

to lat. 30°27′58″ N., long. 89°35′27″ W,;

to lat. 30°28′47″ N., long. 89°35′27″ W.;

to the point of beginning.

Designated altitudes. Surface to 10,000 feet MSL.

Time of designation. Intermittent, 2000 to 0500 local time, as activated by NOTAM at least 24 hours in advance; and 1800 to 2000 local time, November 1 to March 1, as activated by NOTAM at least 24 hours in advance, not to exceed 20 days per year.

Controlling agency. FAA, Houston ARTCC.

Using agency. U.S. Navy, Commander, Naval Special Warfare Command, Naval Special Warfare N31 Branch, Stennis Space Center, Bay St. Louis, MS.

R–4403F Stennis Space Center, MS [New]

Boundaries. Beginning at lat. 30°29′37″ N., long. 89°35′16″ W.;

thence clockwise along a 2.5-NM arc centered

at lat. 30°28′46″ N., long. 89°32′33″ W.;

to lat. 30°26′25″ N., long. 89°31′34″ W.;

to lat. 30°28′46″ N., long. 89°31′34″ W.;

thence counterclockwise along a 0.85-NM arc centered

at lat. 30°28′46″ N., long. 89°32′33″ W.;

to lat. 30°29′37″ N., long. 89°32′33″ W.;

to the point of beginning.

Designated altitudes. 4,000 feet MSL to 10,000 feet MSL.

Time of designation. Intermittent, 2000 to 0500 local time, as activated by NOTAM at least 24 hours in advance; and 1800 to 2000 local time, November 1 to March 1, as activated by NOTAM at least 24 hours in advance, not to exceed 20 days per year.

Controlling agency. FAA, Houston ARTCC.

Using agency. U.S. Navy, Commander, Naval Special Warfare Command, Naval Special Warfare N31 Branch, Stennis Space Center, Bay St. Louis, MS.

* * * * *

Issued in Washington, DC, on August 10 2015.

Gary A. Norek,

Manager, Airspace Policy and Regulations Group.

[FR Doc. 2015–20277 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–13–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2015–16; Order No. 2654]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is noticing a recent Postal Service filing requesting that the Commission initiate an informal rulemaking proceeding to consider changes to analytical principles relating to periodic reports (Proposal Seven). This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* September 25, 2015. *Reply Comments are due:* October 16, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

On August 5, 2015, the Postal Service filed a petition pursuant to 39 CFR 3050.11 requesting that the Commission initiate an informal rulemaking proceeding to consider changes to analytical principles relating to the Postal Service's periodic reports.[1] Proposal Seven is attached to the Petition and proposes an analytical method change relating to the avoided costs for Flats Sequencing System (FSS) workshare discounts. Petition at 1.

This Petition was filed in response to Order No. 2472, which directed the Postal Service ''to file a proposed methodology for determining the costs avoided for the Presorted FSS workshare discounts, as described in the body of [Order No. 2472], within 90 days of the date of [Order No. 2472].'' [2]

II. Summary of Proposal

Under Proposal Seven, the Postal Service seeks to address the avoided costs relating to FSS mail. Petition, Proposal Seven at 1. The Postal Service bifurcates Proposal Seven into the Mail Processing and the Delivery elements of the avoided costs for FSS workshare discounts. *Id.*

A. Section One: Proposed Method for Calculating Mail Processing Cost Avoidances

The Postal Service seeks to modify the modeling methodology used in the USPS–FY14–11 (Docket No. ACR2014) Standard Mail Flats Mail Processing Cost Model to estimate the mail processing cost avoidances of FSS presorted Standard Flats. Petition, Proposal Seven, Section One at 1. The Postal Service expands the Standard Mail Flats Mail Processing Cost Model to identify the unique characteristics and flows of FSS-prepared Standard Flats. *Id.* As part of Library Reference USPS–RM2015–16/1 filed with the Petition, the Postal Service provides three models supporting this section of Proposal Seven. *Id.* The Postal Service also proposes changes to the USPS–FY14–11 (Docket No. ACR2014) Periodicals Flats Mail Processing Cost Model. *Id.* at 4.[3]

There are nine modifications proposed by the Postal Service in Section One of Proposal Seven, all of which apply to the Standard Mail Flats Cost Model. Petition, Proposal Seven, Section One at 4. Two of the proposed modifications also apply to the Periodicals Model. *Id.*

1. Revision of the Methodology Used To Estimate the Proportion of Flats Processed in Mechanized Incoming Secondary Operations (Modification One)

The Postal Service presents a process to estimate the proportion of flat-shaped mail processed in mechanized incoming secondary operations. *Id.* at 4–8. Although over 98 percent of flats destinate in the service territories of plants that have mechanized equipment, certain facilities choose to perform the incoming secondary sortation manually for a variety of reasons, including low volume, service commitments, and

[1] Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Seven), August 5, 2015 (Petition).

[2] Docket No. R2015–4, Order on Revised Price Adjustments for Standard Mail, Periodicals, and Package Services Products and Related Mail Classification Changes, May 7, 2015, at 62 (Order No. 2472).

[3] The proposed changes to the Periodicals Flats Mail Processing Cost Model were filed in Docket No. RM2015–18. *See* Docket No. RM2015–18, Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Nine), August 5, 2015, Attachment at 2.

operating window/capacity restraints. *Id.* at 4–5. The Postal Service asserts that its proposed methodology accounts for the two different technologies performing mechanized incoming secondary sortation—the Automated Flats Sorting Machine 100 (AFSM 100) and the FSS. *Id.* at 5. The Postal Service also represents that its methodology excludes letter shaped mail worked in flat operations, pieces entered in Carrier Route bundles that have broken and therefore require incoming secondary sortation, rejects from FSS operations, and pieces destinating in FSS zones that are not sorted on the FSS. *See id.* at 5–8. This modification applies to both the Standard Mail and Periodicals Flats Mail Processing Cost Models.

2. Changes to Bundle Processing Flows To Account for Increased Mechanized Incoming Secondary Piece Processing

The Postal Service proposes to adjust the bundle flow formulae for consistency with the mechanized incoming secondary piece distribution calculated under Modification One. *See id.* at 8–9. The Postal Service states that bundles for mechanized incoming secondary sortation will not incur an incoming secondary bundle sort. *See id.* The Postal Service explains that bundles for zones worked manually will incur an additional bundle sort at the delivery unit. *Id.* at 9. This modification applies to the Standard Mail Flats Mail Processing Cost Model.

3. Introduction of FSS Bundle Flows

The Postal Service assumes that no FSS bundles will incur a sortation at the delivery unit. *Id.* Aside from this assumption, the Postal Service calculates the bundle flows for FSS bundles using the same methodology used for other bundle types. *Id.* This modification applies to the Standard Mail Flats Mail Processing Cost Model.

4. FSS Presort Piece Model and Costs

The Postal Service states that FSS presorted pieces flow directly into piece sortation on the FSS, bypassing outgoing primary, outgoing secondary, managed mail, and incoming primary operations. *Id.* The Postal Service represents that it models such FSS presorted pieces using the same basic methodology previously used to model piece flows. *Id.* This modification applies to the Standard Mail Flats Mail Processing Cost Model.

5. Updating 5-Digit Piece Model and Costs

The Postal Service represents that 5-Digit pieces do not flow into FSS operations and proposes to update the 5-Digit piece model to reflect this flow. *Id.* at 10. The Postal Service represents that the relative incidence of manual incoming secondary sortation is higher for 5-Digit pieces by a factor of one over one minus the FSS coverage factor. *Id.* This modification applies to the Standard Mail Flats Mail Processing Cost Model.

6. Updating Mixed ADC, ADC, 3-Digit for Incoming Secondary Coverage

The Postal Service proposes to update the area distribution center (ADC), mixed ADC, and 3-Digit models to incorporate the recalculation of the mechanized incoming secondary sortation. *Id.* This modification applies to the Standard Mail Flats Mail Processing Cost Model.

7. Explicit Modeling of Mail Preparation

The Postal Service states that the current model includes the hours associated with mail preparation for the FSS in the calculation of the FSS productivities. *See id.* at 11. However, because such AFSM 100 preparation costs are included in the calculation of the AFSM 100 productivities, the Postal Service observes that a portion of the AFSM 100 preparation costs are allocated incorrectly to FSS prepared pieces through the Cost and Revenue Analysis (CRA) adjustment factor. *See id.* The Postal Service proposes to model AFSM 100 preparation costs using the methodology used in the Periodicals Flats Mail Processing Model. *See id.* This modification applies to the Standard Mail Flats Mail Processing Cost Model.

8. CRA Adjustment Factor Adjusted for the FSS

The Postal Service uses the CRA adjustment factor to calibrate the model to CRA costs and to distribute non-modeled costs to the appropriate rate category. *Id.* The Postal Service states that applying the CRA adjustment factor as is done in the current methodology would distort measured cost avoidances by overdistributing non-modeled costs to FSS pieces. *Id.* at 12. The Postal Service represents that it will calculate the CRA adjustment factor to ensure the non-modeled costs distributed to FSS pieces are equal to those distributed to Five-Digit pieces. *Id.* This modification applies to the Standard Mail Flats Mail Processing Cost Model.

9. FSS Realization Factor

The Postal Service represents that it introduced a FSS Realization Factor to measure the proportion of FSS eligible mail that is processed on the FSS. *Id.* at 12–13. According to the Postal Service, this FSS Realization Factor captures the fact that mail that destinates in a FSS zone and arrives after the end of first-pass processing may be processed on the AFSM 100 rather than the FSS to avoid delay. *Id.* This modification applies to both the Standard Mail and Periodicals Flats Mail Processing Cost Models.

B. Section Two: Proposed Method for Calculating Delivery Costs

The Postal Service proposes a method to disaggregate delivery costs for Periodicals Flats, Bound Printed Matter Flats, Standard Flats and Carrier Route Flats (not including High Density or Saturation) between those destinating in FSS zones and those destinating in non-FSS zones. Petition, Proposal Seven: Section Two at 1. This method uses operational assumptions and models rather than data directly collected from cost systems, and calculates separate delivery costs for the relevant products based on whether pieces are destinating in FSS or non-FSS zones. *Id.* at 3.

The proposed computing method begins with a product's component group costs in three segments: Cost Segment 6, City Carrier In-Office Activities; Cost Segment 7, City Carrier Street Activities; and Cost Segment 10, Rural Carriers Office and Street Activities. *Id.* at 3–9. Within each cost segment, the purpose is to disaggregate costs into FSS zone costs and non-FSS zone costs. *Id.*

III. Initial Commission Action

The Commission establishes Docket No. RM2015–16 for consideration of matters raised by the Petition. Additional information concerning the Petition may be accessed via the Commission's Web site at *http://www.prc.gov.* Interested persons may submit comments on the Petition and Proposal Seven no later than September 25, 2015. Reply comments are due no later than October 16, 2015. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin is designated as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2015–16 for consideration of the matters raised by the Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Seven), filed August 5, 2015.

2. Comments are due no later than September 25, 2015. Reply comments are due no later than October 16, 2015.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Katalin K. Clendenin to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015–20232 Filed 8–14–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2015–18; Order No. 2655]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is noticing a recent Postal Service filing requesting that the Commission initiate an informal rulemaking proceeding to consider changes to analytical principles relating to periodic reports (Proposal Nine). This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* September 8, 2015. *Reply Comments are due:* September 22, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On August 5, 2015, the Postal Service filed a petition pursuant to 39 CFR 3050.11 requesting that the Commission initiate an informal rulemaking proceeding to consider changes to analytical principles relating to the Postal Service's periodic reports.[1] Proposal Nine is attached to the Petition and proposes an analytical method change relating to bottom-up costs for new Periodicals Mail Carrier Route bundle and container entry options. Petition at 1. This Petition was filed in response to Order No. 2472, which directed the Postal Service to ''. . . file a proposed methodology for determining the bottom-up costs for the new Periodicals Mail Carrier Route bundle and container entry options, as described in the body of [Order No. 2472], within 90 days of the date of [Order No. 2472].'' [2]

II. Summary of Proposal

Under Proposal Nine, the Postal Service asserts that no changes to the methodology used to produce avoided cost estimates for Periodicals Mail Carrier Route bundle and container entry options is necessary and instead proposes changes to the model presentation that explicitly identify the bottom-up costs of processing Carrier Route pallets. Petition, Proposal Nine at 1, 2.

When a mailing has sufficient density to prepare 5-Digit or 5-Digit Scheme pallets, the mailer presorts nearly all of the mail on the pallet into Carrier Route bundles. *Id.* at 1. The Postal Service represents that in Fiscal Year 2014, only one-half of one percent of the periodicals on such pallets were prepared in 5-Digit bundles. *Id.* The Postal Service states that the 5-Digit mail on these pallets generally consists of residual pieces for the few routes that lack sufficient density to qualify for Carrier Route rates. *Id.*

The Postal Service represents that for this reason it processes Carrier Route pallets (5-Digit or 5-Digit Scheme pallets containing only Carrier Route bundles) identically to other 5-Digit pallets. *Id.* at 1–2. The Postal Service explains that all pallets are cross-docked to the delivery unit for distribution of bundles to carriers. *Id.* at 2. The Postal Service states that the Carrier Route pallet rate encourages mailers to prepare Carrier Route pallets and to move any residual 5-Digit bundles to containers that would be distributed in the plant. *Id.* The Postal Service represents this enables it to process the residual 5-Digit bundles on the Automated Flats Sorting Machine 100, rather than via manual processing. *Id.*

According to the Postal Service, because the processing of Carrier Route pallets and other 5-Digit pallets does not differ, it proposes no changes to the methodology used to produce estimates of avoided costs. *Id.* The Postal Service represents that the changes it proposes to the USPS–FY14–11 Periodicals Model in Docket No. ACR2014 explicitly identify the costs avoided. *Id.* Further, the Postal Service states that it has incorporated Modifications 1 and 9, described in Section One of Proposal Seven,[3] into the Periodicals Model filed with the Petition as an Excel spreadsheet. *Id.*

III. Initial Commission Action

The Commission establishes Docket No. RM2015–18 for consideration of matters raised by the Petition. Additional information concerning the Petition may be accessed via the Commission's Web site at *http://www.prc.gov.* Interested persons may submit comments on the Petition and Proposal Nine no later than September 8, 2015. Reply comments are due no later than September 22, 2015. Pursuant to 39 U.S.C. 505, Lawrence Fenster is designated as officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2015–18 for consideration of the matters raised by the Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Nine), filed August 5, 2015.

2. Comments are due no later than September 8, 2015. Reply comments are due no later than September 22, 2015.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Lawrence Fenster to serve as officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015–20233 Filed 8–14–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Nine), August 5, 2015 (Petition).

[2] Docket No. R2015–4, Order on Revised Price Adjustments for Standard Mail, Periodicals, and Package Services Products and Related Mail Classification Changes, May 7, 2015, at 63 (Order No. 2472).

[3] Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Seven), August 5, 2015 (Proposal Seven).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2015–0117; FRL–9931–11–Region 6]

Determination of Attainment; Texas; Houston-Galveston-Brazoria 1997 Ozone Nonattainment Area; Determination of Attainment of the 1997 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to determine that the Houston-Galveston-Brazoria (HGB) 8-hour ozone nonattainment area is currently attaining the 1997 ozone National Ambient Air Quality Standard (NAAQS). This determination is based upon certified ambient air monitoring data that show the area has monitored attainment of the 1997 ozone NAAQS for the 2012–2014 monitoring period and continues to monitor attainment of the NAAQS based on preliminary 2015 data. If this proposed determination is made final, the requirements for this area to submit an attainment demonstration, a reasonable further progress (RFP) plan, contingency measures, and other State Implementation Plan (SIP) documents related to attainment of the 1997 ozone NAAQS shall be suspended for so long as the area continues to attain the 1997 ozone NAAQS. This proposed action is consistent with EPA's interpretation of certain requirements of part D of title I of the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before September 16, 2015.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2015–0117, by one of the following methods:

- *www.regulations.gov.* Follow the on-line instructions.
- *Email:* Ms. Wendy Jacques at *jacques.wendy@epa.gov.*
- *Mail or delivery:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

Instructions: Direct your comments to Docket No. EPA–R06–OAR–2015–0117. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.*, copyrighted material), and some may not be publicly available at either location (*e.g.*, CBI). Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional information on submitting comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Ms. Wendy Jacques, (214) 665–7395, *jacques.wendy@epa.gov.* To inspect the hard copy materials, please contact Ms. Jacques or Mr. Bill Deese at (214) 665–7253.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' means EPA.

I. Background

Section 109 of the Act requires the EPA to establish a NAAQS for pollutants that ''may reasonably be anticipated to endanger public health and welfare'' and to develop a primary and secondary standard for each NAAQS. The primary standard is designed to protect human health with an adequate margin of safety and the secondary standard is designed to protect public welfare and the environment. The EPA has set NAAQS for six common air pollutants, referred to as criteria pollutants: carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, and sulfur dioxide. These standards present state and local governments with the minimum air quality levels they must meet to comply with the Act. Also, these standards provide information to residents of the United States about the air quality in their communities.

Ozone is a gas composed of three oxygen atoms. Ground-level ozone is generally not emitted directly from a vehicle's exhaust or an industrial smokestack, but is created by a chemical reaction between volatile organic compounds (VOCs) and oxides of nitrogen (NO_X) in the presence of sunlight.[1] Ozone is known primarily as a summertime air pollutant. Motor vehicle exhaust and industrial emissions, gasoline vapors, chemical solvents and natural sources emit NO_X and VOCs. Urban areas tend to have high concentrations of ground-level ozone, but areas without significant industrial activity and with relatively low vehicular traffic are also subject to increased ozone levels because wind carries ozone and its precursors hundreds of miles from their sources.[2]

On July 18, 1997, the EPA promulgated an 8-hour ozone NAAQS of 0.08 parts per million (ppm), known as the 1997 ozone standard. See 62 FR 38856 and 40 CFR 50.10. Under the EPA regulations at 40 CFR part 50, Appendix I, the 1997 ozone standard is attained when the 3-year average of the annual fourth highest daily maximum 8-hour average ambient ozone concentration is less than or equal to 0.08 ppm.

On April 30, 2004, the EPA designated and classified the 8-county HGB area (consisting of Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery and Waller counties) as a Moderate nonattainment area under the 1997 ozone standard with an attainment date of no later than

[1] VOC and NO_X are often referred to as ''precursors'' to ozone formation.

[2] For additional information on ozone, please visit *www.epa.gov/groundlevelozone.*

June 15, 2010 (see 69 FR 23858 and 69 FR 23951). On June 15, 2007, we received a request from the Governor of Texas seeking voluntary reclassification of the HGB area from a Moderate nonattainment area to a Severe nonattainment area under the 1997 ozone standard, which we approved on October 1, 2008 (73 FR 56983).[3] Subsequently, the State submitted the Reasonable Further Progress (RFP) and Attainment Demonstration (AD) SIPs for the HGB Severe area under the 1997 ozone standard. These RFP and AD SIPs were approved on January 2, 2014 (see 79 FR 51 and 79 FR 57, respectively).

On March 27, 2008 (73 FR 16436), the EPA promulgated a revised 8-hour ozone NAAQS of 0.075 ppm (the 2008 ozone standard). On April 30, 2012, the EPA promulgated designations under the 2008 ozone standard (77 FR 30088) and in that action the EPA designated the 8-county HGB area as a Marginal ozone nonattainment area.[4] The rule to implement the 2008 ozone standard was finalized on March 6, 2014 (see 80 FR 12264) and in that action the EPA revised the Clean Data Policy [5] to include the 2008 ozone NAAQS and any prior ozone NAAQS. That is, upon a determination by the EPA that an area designated nonattainment for the 2008 ozone NAAQS, or for any prior ozone NAAQS, has attained the relevant standard, the requirements for such area to submit attainment demonstrations and associated RFP plans, contingency measures for failure to attain or make reasonable progress and other planning SIPs required under section 182 of the Act related to attainment-of the 2008 ozone NAAQS, or for any prior NAAQS for which the determination has been made, shall be suspended until such time as: (1) The area is redesignated to attainment for that NAAQS or a redesignation substitute is approved as appropriate, at which time the requirements no longer apply; or (2) the EPA determines that the area has violated that NAAQS, at which time the area is again required to submit such plans. See 80 FR 12264, 12317 and 40 CFR 51.1118.

If the EPA's determination that the HGB area is currently attaining the 1997 ozone standard is finalized, 40 CFR 51.1118 provides that the requirements for the TCEQ to submit certain RFP plans, attainment demonstrations, contingency measures and any other attainment planning requirements of the CAA related to attainment of that standard in the HGB area shall be suspended for as long as the area continues to attain the standard. This action is known as a Clean Data Determination or CDD. However, a CDD does not constitute a redesignation to attainment under section 107(d)(3)(E) of the Act, and if the EPA determines that the area subsequently violates the standard, that suspension of the requirement to submit the attainment planning SIP provisions is lifted, and those requirements are once again due. Even though the EPA has finalized revocation of the 1997 eight-hour ozone NAAQS, under 40 CFR 51.1118, an area remains subject to the obligations for a revoked NAAQS until either (i) the area is redesignated to attainment for the 2008 ozone NAAQS; or (ii) the EPA approves a demonstration for the area in a redesignation substitute procedure for a revoked NAAQS per the provisions of § 51.1105(b). Under this redesignation substitute procedure for a revoked NAAQS, and for this limited anti-backsliding purpose, the demonstration must show that the area has attained that revoked NAAQS due to permanent and enforceable emission reductions and that the area will maintain that revoked NAAQS for 10 years from the date of the EPA's approval of this showing. We also note that the CDD does not constitute a Determination of Attainment by an Area's Attainment Date under sections 179(c) and 181(b)(2) of the Act.

II. The EPA's Evaluation of the HGB Data

For ozone, an area is considered to be attaining the 1997 ozone NAAQS if there are no violations, as determined in accordance with 40 CFR part 50, based on three complete, consecutive calendar years of quality-assured air quality monitoring data. Under the EPA regulations at 40 CFR part 50, the 1997 ozone standard is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations at an ozone monitor is less than or equal to 0.08 parts per million (ppm), (*i.e.*, 0.084 ppm, when rounding, based on the truncating conventions in 40 CFR part 50, Appendix I). This 3-year average is referred to as the design value. When the design value is less than or equal to 0.084 ppm at each monitor within the area, then the area is meeting the NAAQS. Also, the data completeness requirement is met when the average percent of days with valid ambient monitoring data is greater than or equal to 90%, and no single year has less than 75% data completeness as determined in Appendix I of 40 CFR part 50. The data must be collected and quality-assured in accordance with 40 CFR part 58, and recorded in the EPA Air Quality System (AQS). The monitors generally should have remained at the same location for the duration of the monitoring period required for demonstrating attainment. For ease of communication, many reports of ozone concentrations are given in parts per billion (ppb); ppb = ppm × 1,000. Thus, 0.084 ppm equals 84 ppb.

The EPA reviewed the HGB area ozone monitoring data from ambient ozone monitoring stations for 2012–2014 and through July 2015. The 2012–2014 data for all the ozone monitors in the HGB area have been quality assured and certified by the EPA. The design value for 2012–2014 is 80 ppb. At the time of this writing, the preliminary ozone data for 2015 are posted on the Texas Commission on Environmental Quality (TCEQ) Web site and in AQS.[6] The data for 2012–2014, and preliminary data for 2015, show that the HGB area is attaining the 1997 ozone NAAQS.

Table 1 shows the fourth-highest daily maximum 8-hour average ozone concentrations for the HGB nonattainment area monitors for the years 2012–2014. (To find the overall design value for the area for a given year, simply find the highest design value from any of the 20 monitors for that year.)

[3] The attainment date for the HGB Severe nonattainment area is as expeditiously as practicable, but not later than June 15, 2019.

[4] The EPA's actions herein do not address the HGB nonattainment area for the 2008 ozone standard.

[5] The EPA initially issued the Clean Data Policy in 1995, ''RFP, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard,'' Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, May 10, 1995. For purposes of the 1997 ozone standard, we codified that policy at 40 CFR 51.918. This codified policy was upheld by the D.C. Circuit in *NRDC* v. *EPA*, 571 F.3d 1245 (D.C. 2009). The policy memo is in the docket for this rulemaking.

[6] See *http://www.tceq.texas.gov/agency/data/ozone_data.html*. Preliminary data for the first quarter of 2015 are posted in AQS and are provided in the docket for this rulemaking.

TABLE 1—THE HGB AREA FOURTH HIGH 8-HOUR OZONE AVERAGE CONCENTRATIONS AND DESIGN VALUES (PPM) FOR 2012–2014 [1]

Site name and AQS No.	4th Highest daily max			Design value (2012–2014)
	2012	2013	2014	
Seabrook Friendship Park, 482011050	0.086	0.067	0.065	0.072
Houston Westhollow, 482010066	0.081	0.077	0.070	0.076
Houston Deer Park #2, 482011039	0.085	0.069	0.063	0.072
Houston North Wayside, 482010046	0.075	0.070	0.062	0.069
Houston Monroe, 482010062	0.085	0.074	0.065	0.074
Conroe Relocated, 483390078	0.082	0.075	0.072	0.076
Houston East, 482011034	0.083	0.069	0.066	0.072
Channelview, 482010026	0.077	0.061	0.064	0.067
Lake Jackson, 480391016	0.071	0.067	0.061	0.066
Baytown Garth, 482011017	0.071	0.061	0.067	0.066
Park Place, 482010416	0.077	0.079	0.066	0.074
Houston Croquet, 482010051	0.079	0.079	0.067	0.075
Houston Aldine, 482010024	0.075	0.074	0.068	0.072
Houston Bayland Park, 482010055	0.077	0.081	0.067	0.075
Clinton, 482011035	0.081	0.067	0.058	0.068
Northwest Harris County, 482010029	0.082	0.080	0.063	0.075
Manvel Croix Park, 480391004	0.087	0.084	0.071	0.080
Lang, 482010047	0.081	0.079	0.064	0.074
Galveston 99th Street, 481671034	0.081	0.064	0.071	0.072
Lynchburg Ferry, 482011015	0.075	0.064	0.059	0.066

[1] These ozone monitors have remained in the same location for the duration of the monitoring period from 2012 to 2014. The TCEQ Web site includes monitoring data for the Texas Avenue site, but Table 1 here does not. Data from the Texas Avenue site is excluded because the site does not meet siting criteria required by 40 CFR part 58 Appendix E. The TCEQ has requested NAAQS exclusion for the pollutants monitored at this site since 2002. The TCEQ ozone monitors and data are posted at *https://www.tceq.texas.gov/cgi-bin/compliance/monops/8hr_attainment.pl.*

As shown in Table 1, the 8-hour ozone design value for 2012–2014, which is based on a three-year average of the fourth-highest daily maximum average ozone concentration at the monitor recording the highest concentrations, is 80 ppb, which meets the 1997 ozone NAAQS. Data for 2015 not yet certified also indicate that the area continues to attain the 1997 ozone NAAQS. In addition, ozone data for 2015 that are available in the EPA AQS database show this area continues to attain the 1997 ozone NAAQS. The AQS data reports for the HGB area for the three years 2012 through 2014 and the first quarter of 2015 are included in the docket for this rulemaking.

III. Proposed Action

In accordance with 40 CFR 51.1118, the EPA is proposing to determine that the HGB 8-hour ozone nonattainment area is currently attaining the 1997 ozone NAAQS. This determination is based upon certified ambient air monitoring data that show the area has monitored attainment of the 1997 ozone NAAQS for the 2012–2014 monitoring period and continues to monitor attainment of the NAAQS based on preliminary 2015 data. Thus the requirements for such area to submit attainment demonstrations and associated reasonably available control measures, RFP plans, contingency measures for failure to attain or make reasonable progress and other planning SIPs related to attainment of the 1997 ozone NAAQS shall be suspended until such time as: (1) The area is redesignated to attainment for the 1997 ozone NAAQS or a redesignation substitute is approved as appropriate, at which time the requirements no longer apply; or (2) the EPA determines that the area has violated the 1997 ozone NAAQS, at which time the area is again required to submit such plans. This proposal is consistent with our interpretation of certain requirements of part D of title I of the Act.

IV. Statutory and Executive Order Reviews

This action proposes to make a determination of attainment based on air quality, and would, if finalized, result in the suspension of certain Federal requirements, and it would not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

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

In addition, this proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it merely makes a determination based on air quality data.

List of Subjects in 40 CFR Part 52

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

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

Dated: August 3, 2015.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2015–20026 Filed 8–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2013–0534; FRL–9932–45–Region 9]

Withdrawal of Approval and Disapproval of Air Quality Implementation Plans; California; San Joaquin Valley; Contingency Measures for the 1997 $PM_{2.5}$ Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to withdraw a May 22, 2014 final action approving a state implementation plan (SIP) revision submitted by the State of California under the Clean Air Act (CAA) to address contingency measure requirements for the 1997 annual and 24-hour national ambient air quality standards (NAAQS) in the San Joaquin Valley. Simultaneously, EPA is proposing to disapprove this SIP submission. These proposed actions are in response to a decision issued by the U.S. Court of Appeals for the Ninth Circuit (*Committee for a Better Arvin* v. *EPA,* 786 F.3d 1169 (9th Cir. 2015)) remanding EPA's approval of a related SIP submission and rejecting EPA's rationale for approving plan submissions that rely on California mobile source control measures to meet SIP requirements such as contingency measures, which was a necessary basis for the May 22, 2014 final rule.

DATES: Any comments must arrive by September 16, 2015.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2013–0534, by one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.
- *Email: lo.doris@epa.gov.*
- *Mail or delivery:* Doris Lo, (AIR–2), U.S. Environmental Protection Agency Region 9, 75 Hawthorne Street, San Francisco, CA 94105.

Instructions: All comments will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comments due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials in person, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section below.

FOR FURTHER INFORMATION CONTACT: Doris Lo, Air Planning Office (AIR–2), (415) 972–3959, *lo.doris@epa.gov.*

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

Table of Contents

I. Background

On July 18, 1997, EPA established new national ambient air quality standards (NAAQS) for particles less than or equal to 2.5 micrometers (μm) in diameter ($PM_{2.5}$), including an annual standard of 15.0 micrograms per cubic meter (μg/m^3) based on a 3-year average of annual mean $PM_{2.5}$ concentrations and a 24-hour (daily) standard of 65 μg/m^3 based on a 3-year average of 98th percentile 24-hour $PM_{2.5}$ concentrations.[1] Effective April 5, 2005, EPA designated the San Joaquin Valley (SJV) area in California as nonattainment for the 1997 annual and 24-hour $PM_{2.5}$ NAAQS.[2] The SJV $PM_{2.5}$ nonattainment area is located in the southern half of California's central valley and includes all or part of eight counties: San Joaquin, Stanislaus, Merced, Madera, Fresno, Tulare, Kings, and the valley portion of Kern.[3] The local air district with primary responsibility for developing state implementation plans (SIPs) to attain the NAAQS in this area is the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD or District).

Between 2007 and 2011, California made six SIP submittals to address nonattainment area planning requirements for the 1997 annual and 24-hour $PM_{2.5}$ NAAQS in the SJV.[4] We refer to these submittals collectively as the ''2008 $PM_{2.5}$ Plan.'' On November 9, 2011, EPA approved all elements of the 2008 $PM_{2.5}$ Plan except for the contingency measures, which EPA disapproved for failure to satisfy the requirements of CAA section 172(c)(9).[5] On July 3, 2013, the State made a new submission to meet the contingency measure requirements for the 1997 $PM_{2.5}$ NAAQS in the SJV (2013 Contingency Measure Submittal) to correct the deficiencies identified in EPA's November 2011 action disapproving the contingency measure element of the 2008 $PM_{2.5}$ Plan.[6]

On May 22, 2014, EPA fully approved the 2013 Contingency Measure Submittal based on the Agency's conclusion that this SIP submittal corrected then outstanding deficiencies in the CAA section 172(c)(9) contingency measures for the 1997

[1] 62 FR 36852 (July 18, 1997) and 40 CFR 50.7. Effective December 18, 2006, EPA strengthened the 24-hour $PM_{2.5}$ NAAQS by lowering the level to 35 μg/m^3. 71 FR 61144 (October 17, 2006) and 40 CFR 50.13. Effective March 18, 2013, EPA strengthened the primary annual $PM_{2.5}$ NAAQS by lowering the level to 12 μg/m^3. 78 FR 3086 (January 15, 2013) and 40 CFR 50.18. In this preamble, all references to the $PM_{2.5}$ NAAQS, unless otherwise specified, are to the 1997 24-hour standard (65 μg/m^3) and annual standard (15.0 μg/m^3) as codified in 40 CFR 50.7.

[2] 70 FR 944 (January 5, 2005), codified at 40 CFR 81.305.

[3] For a precise description of the geographic boundaries of the San Joaquin Valley nonattainment area, see 40 CFR 81.305.

[4] 76 FR 69896 at n. 2 (November 9, 2011) (final action on 2008 $PM_{2.5}$ Plan).

[5] *Id.* at 69924.

[6] 78 FR 53113, 53115–53116 (August 28, 2013) (proposed action on Contingency Measure SIP).

$PM_{2.5}$ NAAQS.[7] Among other things, the 2013 Contingency Measure Submittal relied on the ongoing implementation of California's mobile source control program as a basis for satisfying the contingency measure requirements in CAA section 172(c)(9). Specifically, the 2013 Contingency Measure Submittal relied on California mobile source measures to achieve 21 tons per day (tpd) of reductions in emissions of nitrogen oxides (NO_X) in 2015, roughly two-thirds of the total amount of NO_X emission reductions (31.6 tpd) necessary to achieve one year's worth of reasonable further progress (RFP) in the SJV.[8] In its May 22, 2014 final action on the 2013 Contingency Measure Submittal, EPA determined that CARB's continuing implementation of these mobile source control measures in 2015, together with other fully-adopted measures implemented by the District in the same timeframe, would provide for an appropriate level of continued emission reduction progress should the SJV area fail to attain the 1997 $PM_{2.5}$ NAAQS by the applicable attainment date, which was April 5, 2015, thereby meeting the requirement for contingency measures for failure to attain.[9] With respect to the requirement for contingency measures for failure to meet RFP requirements, EPA determined that this requirement was moot because the District had already met the RFP requirements relevant to the 2008 $PM_{2.5}$ Plan by the time of EPA's May 22, 2014 action.[10]

Several environmental and community organizations filed a petition for review of EPA's November 9, 2011 action on the 2008 $PM_{2.5}$ Plan, arguing, among other things, that the 2008 $PM_{2.5}$ Plan had calculated the necessary emission reductions and forecasts in part based on state-adopted mobile source measures that are not themselves incorporated into the federally enforceable plan, in violation of the CAA.[11] At that time, EPA's longstanding and consistent practice had been to allow California SIPs to rely on emission reduction credit for state mobile source rules waived or authorized by EPA under section 209 of the Act (''waiver measures'') to meet certain SIP requirements without requiring approval of those control measures into the SIP under section 110 of the Act. On May 20, 2015, the U.S. Court of Appeals for the Ninth Circuit granted the petition with respect to this issue, holding that EPA violated the CAA by approving the 2008 $PM_{2.5}$ Plan even though the plan did not include the waiver measures on which the plan relied to achieve its emission reduction goals. *Committee for a Better Arvin, et al.* v. *EPA,* 786 F.3d 1169 (9th Cir. 2015) (*CBA*) (partially granting and partially denying petition for review). The court rejected EPA's arguments supporting the Agency's longstanding practice, finding that section 110(a)(2)(A) of the Act plainly mandates that all control measures on which states rely to attain the NAAQS must be ''included'' in the SIP and subject to enforcement by EPA and citizens. The court remanded EPA's November 9, 2011 action for further proceedings consistent with the decision.

Separately, environmental and community organizations also filed a petition for review of EPA's May 22, 2014 action on the 2013 Contingency Measure Submittal, arguing, among other things, that EPA violated the CAA by approving that submittal even though it did not include the waiver measures on which it relied to achieve the necessary emission reductions to meet contingency measure requirements.[12] On June 10, 2015, EPA filed an unopposed motion for voluntary remand of the May 22, 2014 final rule without vacatur based, *inter alia,* on the Agency's substantial and legitimate need to reexamine this rulemaking in light of the Ninth Circuit's May 20, 2015 decision in *CBA*.[13] As explained in EPA's motion, the 2013 Contingency Measure Submittal that EPA approved in the May 22, 2014 rulemaking relied upon waiver measures to achieve a significant percentage of the emission reductions necessary to comply with the statutory requirement for contingency measures, and these waiver measures are not included in the SIP.[14] EPA moved the court for an order remanding the May 22, 2014 final rule to allow the Agency to reconsider it in light of the *CBA* decision.[15] On June 15, 2015, the Ninth Circuit granted EPA's motion and remanded the petition for review to EPA.[16]

II. Proposed Action and Clean Air Act Consequences

As noted above, the Ninth Circuit rejected EPA's prior interpretation of the CAA under which EPA had allowed California SIPs to rely on waiver measures without requiring approval of those measures into the SIP in accordance with section 110 of the Act. This interpretation formed a necessary basis for EPA's approval of the 2013 Contingency Measure Submittal.[17] In response to the court's ruling in *CBA,* we are proposing to withdraw our May 22, 2014 approval of the 2013 Contingency Measure Submittal (79 FR 29327) because it was predicated on an interpretation of the CAA that has been rejected by the Ninth Circuit. For the same reason, we are proposing to disapprove the 2013 Contingency Measure Submittal for failure to satisfy the requirements of the Act. This proposed withdrawal and disapproval, if finalized, would have the effect of removing the 2013 Contingency Measure Submittal from the applicable California SIP and deleting the provisions in 40 CFR 52.220(c) where EPA's approval of the SIP submittal is currently codified.[18]

Under section 179(a) of the CAA, final disapproval of a SIP submittal that addresses a requirement of part D, title I of the Act or is required in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (SIP Call) starts a mandatory sanctions clock. Disapproval of a SIP element also triggers the requirement under CAA section 110(c) for EPA to promulgate a FIP no later than 2 years from the date of the disapproval unless the State corrects the deficiency, and the Administrator approves the plan or plan revision, before the Administrator promulgates such FIP.

EPA is proposing to determine that this disapproval of the 2013 Contingency Measure Submittal does not start a mandatory sanctions clock or FIP clock because the specific type of contingency measure at issue in that submittal is no longer a required attainment plan element under the facts and circumstances of this situation. CARB submitted the 2013 Contingency Measure Submittal to address the contingency measure requirement in CAA section 172(c)(9) as applied to the 2008 $PM_{2.5}$ Plan, which provided for attainment of the 1997 $PM_{2.5}$ NAAQS by April 5, 2015, the latest permissible attainment date for this area under

[7] 79 FR 29327 (May 22, 2014) (final action on Contingency Measure SIP).

[8] 78 FR 53113, 53123 (August 28, 2013) and 79 FR 29327, 29336–29337 (May 22, 2014).

[9] 78 FR 53113, 53123 and 79 FR 29327, 29350.

[10] 79 FR 29327, 29350.

[11] *Committee for a Better Arvin et al.* v. *EPA,* Case No. 11–73924 (9th Cir.).

[12] *Medical Advocates for Healthy Air et al.* v. *EPA,* Case No. 14–72219 (9th Cir.).

[13] *Medical Advocates for Healthy Air et al.* v. *EPA,* Case No. 14–72219 (9th Cir.), United States Unopposed Motion for Voluntary Remand of the Rule at Issue Without Vacatur, Docket Entry 29–1.

[14] *Id.*

[15] *Id.*

[16] *Medical Advocates for Healthy Air et al.* v. *EPA,* Case No. 14–72219 (9th Cir.), Order, Docket Entry 30.

[17] 79 FR 29327, 29336–37 (May 22, 2014).

[18] *See* 40 CFR 52.220(c)(438)(ii).

subpart 1 of part D, title I of the Act.[19] Thus, CARB intended the specific measures to be contingency measures that would apply in the event of a failure to attain by April 5, 2015. However, intervening events have affected the applicable requirements for contingency measures for this area. A January 2013 decision of the D.C. Circuit Court of Appeals (*NRDC* v. *EPA,* 706 F.3d 428 (D.C. Cir. 2013)) held that EPA must implement the 1997 $PM_{2.5}$ NAAQS in accordance with the requirements of subpart 4 of Part D, title I of the Act. In order to address the requirements of subpart 4, EPA promulgated a rulemaking to classify all existing $PM_{2.5}$ nonattainment areas, including SJV, as ''Moderate'' nonattainment areas and to provide additional time for states to make or supplement SIP submissions in order to meet the requirements of subpart 4.[20] On April 7, 2015, EPA determined that the SJV area could not attain by the applicable attainment date (*i.e.,* April 5, 2015) and therefore reclassified the area from ''Moderate'' to ''Serious.'' As a consequence of the SJV area's reclassification as a Serious area for the 1997 $PM_{2.5}$ NAAQS, California is now required to submit a Serious area plan, including both a demonstration that the plan provides for attainment of the 1997 $PM_{2.5}$ standards in the SJV by the Serious area attainment date, which is December 31, 2015, and contingency measures to be implemented if the area fails to make RFP or to attain by that date.[21] Another consequence of this reclassification, however, is that the specific requirement for contingency measures for failure to attain as a Moderate area plan requirement was superseded and eliminated.[22] Thus, the specific contingency measures at issue in the 2013 Contingency Measure Submittal are no longer required and disapproval of those specific measures should not be a basis for sanctions or a FIP under these facts and circumstances.

Our proposed disapproval of the 2013 Contingency Measure Submittal, if finalized, would not trigger sanctions or FIP clocks because the contingency measure requirement that this SIP submittal addressed has been superseded by different planning obligations under subpart 4 of part D, title I of the Act. That is, because the State submitted the 2013 Contingency Measure Submittal to address a contingency measure requirement for failure to attain by a statutory attainment date that no longer applies to the area (April 5, 2015), this SIP submittal no longer addresses an applicable requirement of part D, title I of the Act, and our disapproval of it therefore would not trigger sanctions. For the same reason, our disapproval of the 2013 Contingency Measure Submittal would not create any deficiency in a mandatory component of the SIP for this area and, therefore, would not trigger the obligation for EPA to promulgate a FIP under section 110(c) to address this issue.

III. Request for Public Comment

We will accept comments from the public on these proposals for the next 30 days. The deadline and instructions for submission of comments are provided in the ''Date'' and ''Addresses'' sections at the beginning of this preamble.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

This action is not a ''significant regulatory action'' under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et. seq.,* because this proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act will not in-and-of itself create any new information collection burdens but simply disapproves certain State requirements submitted for inclusion into the SIP. Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant impact on a substantial number of small entities. This rule does not impose any requirements or create impacts on small entities. This proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act will not in-and-of itself create any new requirements but simply disapproves certain State requirements submitted for inclusion into the SIP. Accordingly, it affords no opportunity for EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables or exemptions from all or part of the rule. The fact that the Clean Air Act prescribes that various consequences (*e.g.,* higher offset requirements) may or will result from disapproval actions does not mean that EPA either can or must conduct a regulatory flexibility analysis for this action. Therefore, this action will not have a significant economic impact on a substantial number of small entities.

We continue to be interested in the potential impacts of this proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector.'' EPA has determined that the proposed disapproval action does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This action proposes to

[19] 80 FR 1482, 1483 at n. 10 (January 12, 2015) (proposed rule to reclassify SJV as Serious nonattainment for 1997 $PM_{2.5}$ NAAQS).

[20] 79 FR 31566 (June 2, 2014).

[21] 80 FR 18528 (April 7, 2015). California has requested an extension of the Serious area attainment date pursuant to CAA section 188(e), and EPA is currently evaluating that request. *See* letter dated June 25, 2015, from Richard Corey, Executive Officer, California Air Resources Board, to Jared Blumenfeld, Regional Administrator, EPA Region 9, transmitting ''2015 Plan for the $PM_{2.5}$ Standard.''

[22] EPA does not interpret the requirement for failure-to-attain contingency measures to apply to Moderate $PM_{2.5}$ nonattainment areas that cannot practicably attain the NAAQS by the statutory attainment date. Rather, EPA believes it is appropriate for the state to identify and adopt attainment contingency measures as part of the Serious area attainment plan that it will develop once EPA reclassifies the area. *See* 59 FR 41998, 42015 (August 16, 1994).

disapprove pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

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, as specified in Executive Order 13132, because it merely disapproves certain State requirements for inclusion into the SIP and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175, Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP EPA is proposing to disapprove would not apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act will not in-and-of itself create any new regulations but simply disapproves certain State requirements submitted for inclusion into the SIP.

H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The EPA believes that this action is not subject to requirements of Section 12(d) of NTTAA because application of those requirements would be inconsistent with the Clean Air Act.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this rulemaking.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen oxides, Sulfur oxides, Particulate matter.

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

Dated: August 6, 2015.

Jared Blumenfeld,

EPA Regional Administrator, Region 9.

[FR Doc. 2015–20240 Filed 8–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[EPA–HQ–OAR–2015–0208; FRL–9931–95–OAR]

RIN 2060–AS64

Relaxation of the Federal Reid Vapor Pressure Gasoline Volatility Standard for Mecklenburg and Gaston Counties, North Carolina

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a request from the state of North Carolina for the EPA to relax the Reid Vapor Pressure (RVP) standard applicable to gasoline introduced into commerce from June 1 to September 15 of each year for Mecklenburg and Gaston counties, North Carolina. Specifically, the EPA is proposing to amend the regulations to allow the RVP standard for Mecklenburg and Gaston counties to rise from 7.8 pounds per square inch (psi) to 9.0 psi for gasoline. The EPA has preliminarily determined that this change to the federal RVP regulation is consistent with the applicable provisions of the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 16, 2015 unless a public hearing is requested by September 1, 2015. If the EPA receives such a request, we will publish information related to the timing and location of the hearing and a new deadline for public comment.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2015–0208, to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you

consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit *http://www.epa.gov/dockets/comments.html* for instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make.

The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Patty Klavon, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, Michigan, 48105; telephone number: (734) 214–4476; fax number: (734) 214–4052; email address: *klavon.patty@epa.gov.*

SUPPLEMENTARY INFORMATION: The contents of this preamble are listed in the following outline:

I. General Information

A. This Proposed Rule Is Published Parallel to a Direct Final Rule

In the ''Rules and Regulations'' section of this **Federal Register**, the EPA is making this revision as a direct final rule without prior proposal because the EPA views this revision as noncontroversial and anticipates no adverse comment. The rationale for this rulemaking is described both in this proposal and in the direct final rule.

The regulatory text for this proposed rule is included in the direct final rule, and parties should review that rule for the regulatory text. If the EPA receives no adverse comment, the EPA will not take further action on this proposed rule. If the EPA receives adverse comment on this rule or any portion of this rule, the EPA will withdraw the direct final rule or the portion of the rule that received adverse comment. All public comments received will then be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this rulemaking. Any parties interested in commenting must do so at this time.

B. Does this action apply to me?

Entities potentially affected by this proposed rule are fuel producers and distributors who do business in North Carolina.

Examples of potentially regulated entities	NAICS [1] codes
Petroleum refineries	324110
Gasoline Marketers and Distributors	424710 424720
Gasoline Retail Stations	447110
Gasoline Transporters	484220 484230

[1] North American Industry Classification System.

The above table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. The table lists the types of entities of which the EPA is aware that potentially could be affected by this proposed rule. Other types of entities not listed on the table could also be affected. To determine whether your organization could be affected by this proposed rule, you should carefully examine the regulations in 40 CFR 80.27. If you have questions regarding the applicability of this action to a particular entity, call the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

C. What is the agency's authority for taking this action?

The statutory authority for this action is granted to the EPA by Sections 211(h) and 301(a) of the Clean Air Act, as amended; 42 U.S.C. 7545(h) and 7601(a).

II. Public Participation

The EPA will not hold a public hearing on this matter unless a request is received by the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble by September 1, 2015. If the EPA receives such a request, we will publish information related to the timing and location of the hearing and a new deadline for public comment.

III. Background and Proposal

A. Summary of the Proposal

The EPA is proposing to approve a request from the state of North Carolina to change the summertime RVP standard for Mecklenburg and Gaston counties, North Carolina from 7.8 psi to 9.0 psi by amending the EPA's regulations at 40 CFR 80.27(a)(2). In a previous rulemaking, the EPA approved a redesignation request and maintenance plan for the Charlotte-Gastonia-Salisbury, North Carolina 2008 ozone area (''the Charlotte area'') and a CAA section 110(l) non-interference demonstration that relaxing the federal RVP requirement from 7.8 psi to 9.0 psi for gasoline sold from June 1 to September 15 of each year in Mecklenburg and Gaston counties would not interfere with maintenance of any NAAQS in the Charlotte area, including the 2008 ozone NAAQS, or with any other applicable CAA requirement. Mecklenburg and Gaston counties are part of the Charlotte area. For more information on North Carolina's redesignation request and maintenance plan for the Charlotte area, please refer to Docket ID. No. EPA–R04–OAR–2015–0275 for the rulemaking that was signed on July 17, 2015.

The preamble for this rulemaking is organized as follows: Section III.B. provides the history of the federal gasoline volatility regulation. Section III.C. describes the policy regarding relaxation of gasoline volatility standards in ozone nonattainment areas that are redesignated as attainment areas. Section III.D. provides information specific to North Carolina's request for Mecklenburg and Gaston counties. Finally, Section IV. briefly discusses the associated direct final rule.

B. History of the Gasoline Volatility Requirement

On August 19, 1987 (52 FR 31274), the EPA determined that gasoline nationwide was becoming increasingly volatile, causing an increase in evaporative emissions from gasoline-powered vehicles and equipment. Evaporative emissions from gasoline, referred to as volatile organic compounds (VOC), are precursors to the formation of tropospheric ozone and contribute to the nation's ground-level ozone problem. Exposure to ground-level ozone can reduce lung function, thereby aggravating asthma and other respiratory conditions, increase susceptibility to respiratory infection, and may contribute to premature death in people with heart and lung disease.

The most common measure of fuel volatility that is useful in evaluating gasoline evaporative emissions is RVP. Under CAA section 211(c), the EPA promulgated regulations on March 22, 1989 (54 FR 11868) that set maximum limits for the RVP of gasoline sold during the regulatory control periods that were established on a state-by-state

basis in the final rule. The regulatory control periods addressed the portion of the year when peak ozone concentrations were expected. These regulations constituted Phase I of a two-phase nationwide program, which was designed to reduce the volatility of gasoline during the high ozone season. On June 11, 1990 (55 FR 23658), the EPA promulgated more stringent volatility controls as Phase II of the volatility control program. These requirements established maximum RVP standards of 9.0 psi or 7.8 psi (depending on the state, the month, and the area's initial ozone attainment designation with respect to the 1-hour ozone NAAQS.)

The 1990 CAA Amendments established a new section 211(h) to address fuel volatility. CAA section 211(h) requires the EPA to promulgate regulations making it unlawful to sell, offer for sale, dispense, supply, offer for supply, transport, or introduce into commerce gasoline with an RVP level in excess of 9.0 psi during the high ozone season. CAA section 211(h) also prohibits the EPA from establishing a volatility standard more stringent than 9.0 psi in an attainment area, except that the EPA may impose a lower (more stringent) standard in any former ozone nonattainment area redesignated to attainment.

On December 12, 1991 (56 FR 64704), the EPA modified the Phase II volatility regulations to be consistent with CAA section 211(h). The modified regulations prohibited the sale of gasoline with an RVP above 9.0 psi in all areas designated attainment for ozone, effective January 13, 1992. For areas designated as nonattainment, the regulations retained the original Phase II standards published on June 11, 1990 (55 FR 23658), which included the 7.8 psi ozone season limitation for certain areas. As stated in the preamble to the Phase II volatility controls and reiterated in the proposed change to the volatility standards published in 1991, the EPA will rely on states to initiate changes to their respective volatility programs. The EPA's policy for approving such changes is described below in Section III.C.

The state of North Carolina has initiated this change by requesting that the EPA relax the 7.8 psi gasoline RVP standard to 9.0 psi for Mecklenburg and Gaston counties, which are subject to the 7.8 gasoline RVP requirement during the summertime ozone season. Accordingly, the state of North Carolina provided a technical demonstration showing that relaxing the federal gasoline RVP requirements in the two counties from 7.8 psi to 9.0 psi would not interfere with maintenance of any NAAQS in the Charlotte area, including the 2008 ozone NAAQS, or with any other applicable CAA requirement.

C. The EPA's Policy Regarding Relaxation of Gasoline Volatility Standards in Ozone Nonattainment Areas That Are Redesignated to Attainment Areas

As stated in the preamble for the EPA's amended Phase II volatility standards (56 FR 64706), any change in the gasoline volatility standard for a nonattainment area that was subsequently redesignated as an attainment area must be accomplished through a separate rulemaking that revises the applicable standard for that area. Thus, for former 1-hour ozone nonattainment areas where the EPA mandated a Phase II volatility standard of 7.8 psi RVP in the December 12, 1991 rulemaking, the federal 7.8 psi gasoline RVP requirement remains in effect, even after such an area is redesignated to attainment, until a separate rulemaking is completed that relaxes the federal gasoline RVP standard in that area from 7.8 psi to 9.0 psi.

As explained in the December 12, 1991 rulemaking, the EPA believes that relaxation of an applicable gasoline RVP standard is best accomplished in conjunction with the redesignation process. In order for an ozone nonattainment area to be redesignated as an attainment area, CAA section 107(d)(3) requires the state to make a showing, pursuant to CAA section 175A, that the area is capable of maintaining attainment for the ozone NAAQS for ten years. Depending on the area's circumstances, this maintenance plan will either demonstrate that the area is capable of maintaining attainment for ten years without the more stringent volatility standard or that the more stringent volatility standard may be necessary for the area to maintain its attainment with the ozone NAAQS. Therefore, in the context of a request for redesignation, the EPA will not relax the gasoline volatility standard unless the state requests a relaxation and the maintenance plan demonstrates to the satisfaction of the EPA that the area will maintain attainment for ten years without the need for the more stringent volatility standard.

North Carolina is requesting relaxation of the federal gasoline RVP standard from 7.8 psi to 9.0 psi for Mecklenburg and Gaston counties concurrent with its request that the EPA approve a redesignation request and maintenance plan for the Charlotte area for the 2008 ozone NAAQS.

D. North Carolina's Request To Relax the Federal Gasoline RVP Requirement for Mecklenburg and Gaston Counties

On March 11, 2015, the state of North Carolina, through the North Carolina Department of Environment and Natural Resources (NCDENR), submitted a redesignation request and maintenance plan for the Charlotte area, which was classified as Marginal for the 2008 ozone NAAQS. Mecklenburg and Gaston counties are part of the Charlotte area. Additionally, the state submitted a CAA section 110(l) non-interference demonstration that removal of the federal RVP requirement of 7.8 psi for gasoline during the summertime ozone season in Mecklenburg and Gaston counties would not interfere with maintenance of any NAAQS, or with any other applicable CAA requirement. Specifically, the state provided a technical demonstration showing that relaxing the federal gasoline RVP requirement in the two counties from 7.8 psi to 9.0 psi would not interfere with maintenance of any NAAQS in the Charlotte area, of which the two counties are part, including the 2008 ozone NAAQS, or with any other applicable CAA requirement.

In a rulemaking that was signed on July 17, 2015, the EPA evaluated and approved North Carolina's March 11, 2015 redesignation request and maintenance plan for the Charlotte area. See Docket ID. No. EPA–R04–OAR–2015–0275. In a separate rulemaking signed on July 17, 2015, the EPA approved North Carolina's non-interference demonstration for Mecklenburg and Gaston counties. See Docket ID. No. EPA–R04–OAR–2015–0260.[1]

Both rulemakings were subject to public notice-and-comment. The EPA received two comments on the redesignation request and maintenance plan rulemaking, and those comments were addressed in the final rule for that rulemaking. The comments received can be found in the docket for that rulemaking (Docket ID. No. EPA–R04–OAR–2015–0275). No comments were received on the non-interference demonstration for Mecklenburg and Gaston counties (Docket ID. No. EPA–R04–OAR–2015–0260).

In this action, the EPA is taking the second and final step in the process by proposing to approve North Carolina's request to relax the summertime ozone season gasoline RVP standard for Mecklenburg and Gaston counties from 7.8 psi to 9.0 psi. Specifically, the EPA

[1] On March 11, 2015, the NCDENR requested that the EPA parallel process the approval of the submission.

is proposing to amend the applicable gasoline RVP standard to allow the gasoline RVP requirements to rise from 7.8 psi to 9.0 psi provided at 40 CFR 80.27(a)(2) for the two counties. This proposal to approve North Carolina's request to relax the summertime ozone season gasoline RVP standard for Mecklenburg and Gaston counties from 7.8 psi to 9.0 psi is based on the previous approval of North Carolina's March 11, 2015 redesignation request and maintenance plan and non-interference demonstration. It is also based on the fact that the Charlotte area is currently in attainment for the both the 1997 ozone NAAQS and the 2008 ozone NAAQS.

IV. Direct Final Rule

A direct final rule that would make the same changes as those proposed in this action appears in the Rules and Regulations section of this **Federal Register**. The EPA is taking direct final action on these revisions because the EPA views the revisions as noncontroversial and anticipates no adverse comment. The EPA has explained the reasons for the amendments in this proposal and in the direct final rule. If no adverse comments are received, no further action will be taken on the proposal, and the direct final rule will become effective as provided in that action.

If the EPA receives adverse comments on the rule or any portion of the rule, the EPA will withdraw the direct final rule or the portion of the rule that received adverse comment. The EPA will publish a timely withdrawal in the **Federal Register** indicating which provisions are being withdrawn. All public comments received will then be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on the subsequent final action. Any parties interested in commenting must do so at this time.

The changes to the regulatory text proposed in this document are identical to those for the direct final rule published in the Rules and Regulations section of this **Federal Register**. For further information, including the regulatory revisions, see the direct final rule published in a separate part of this **Federal Register**.

V. Statutory and Executive Order Reviews

For a complete discussion of all the administrative requirements applicable to this action, see the direct final rule in the Rules and Regulations section of this **Federal Register**.

VI. Legal Authority

The statutory authority for this action is granted to the EPA by Sections 211(h) and 301(a) of the Clean Air Act, as amended; 42 U.S.C. 7545(h) and 7601(a).

List of Subjects in 40 CFR Part 80

Environmental protection, Administrative practice and procedures, Air pollution control, Fuel additives, Gasoline, Motor vehicle and motor vehicle engines, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

Dated: August 5, 2015.

Gina McCarthy,

Administrator.

[FR Doc. 2015–20245 Filed 8–14–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 219

[Docket No. 150413360–5701–03]

RIN 0648–BF02

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Northeast Fisheries Science Center Fisheries Research; Correction

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

ACTION: Proposed rule; correction; extension of public comment period.

SUMMARY: This document contains corrections to the preamble to the proposed rule published on August 6, 2015, that would establish a framework for authorizing the take of marine mammals incidental to the NEFSC's fisheries research activities in the Atlantic coast region for a five-year period, 2015–2020. This action is necessary to correct typographical errors in the annual estimates presented for Level B harassment of northern bottlenose whales (*Hyperoodon ampullatus*) from 10 to 12. This change accounts for the annual estimate of level B harassment for this species in both inshore (10 individuals) and offshore waters (2 individuals) in the Atlantic coast region.

The **Federal Register** proposed rule published on July 9, 2015, indicated that written comments were due by August 10, 2015, which allowed 30 calendar days for public input. On August 6, 2015, NMFS published a correction and extended the public comment period to August 17, 2015. NMFS has decided to extend the public comment period by an additional 30 calendar days for public input.

DATES: The comment period for the proposed rule published July 9, 2015, at 80 FR 39542, extended August 6, 2015, at 80 FR 46939, has been further extended. NMFS must receive written comments and information no later than September 16, 2015.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2015–0078, by any of the following methods:

- Electronic submission: Submit all electronic public comments via the federal e-Rulemaking Portal. Go to *www.regulations.gov*, enter 0648–BF02 in the ''Search'' box, click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- Mail: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East West Highway, Silver Spring, MD 20910.

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. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. To help NMFS process and review comments more efficiently, please use only one method to submit comments. All comments received are a part of the public record. NMFS will generally post the comments on *www.regulations.gov* 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. NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Jeannine Cody, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

NMFS published a proposed rule on July 9, 2015 (80 FR 39542) to establish a framework for authorizing the take of marine mammals incidental to the NEFSC's fisheries research activities in

the Atlantic coast region for a five-year period, 2015–2020. NMFS refers the reader to the July 9, 2015, **Federal Register** notice (80 FR 39542) for background information concerning the proposed regulations. The information presented in the notice of proposed rulemaking is not repeated here. NMFS also published a correction to the proposed rule on August 6, 2015 (80 FR 46939). This correction revises the description contained in the preamble of the estimates of northern bottlenose whales (*Hyperoodon ampullatus*) to be taken by Level B harassment from 10 to 12. This correction presents the total annual estimate of level B harassment for this species in both inshore (10) and offshore waters (2) in the Atlantic coast region. The correction does not affect NMFS' preliminary determinations presented in the proposed rule (80 FR 39542, July 9, 2015).

Need for Correction

As published, the preamble to the proposed regulations contains errors or typographical mistakes which need to be clarified. These errors and omissions were also incorrectly recorded within the proposed regulatory text and should be clarified there as well.

1. On page 46941, in Table 20, the entries for northern bottlenose whales are corrected to read as follows:

TABLE 20—SUMMARY INFORMATION RELATED TO PROPOSED ANNUAL TAKE AUTHORIZATION IN THE ATLANTIC COAST REGION, 2015–2020

Species [1]	Proposed total annual Level B harassment authorization	Percent of estimated population	Proposed total M/SI + Level A authorization, 2015–2020	Estimated maximum annual M/SI + Level A [2]	PBR [3]	% PBR [4]	Stock trend [5]
*	*	*	*	*	*	*	
Northern bottlenose whale	12	n/a	0	0	n/a	—	?
*	*	*	*	*	*	*	

[1] For species with multiple stocks in the Atlantic coast regions or for species groups (*Kogia spp.* and Mesoplodont beaked whales), indicated level of take could occur to individuals from any stock or species (not including coastal and estuarine stocks of bottlenose dolphins).

[2] This column represents the total number of incidents of M/SI + Level A that could potentially accrue to the specified species or stock and is the number carried forward for evaluation in the negligible impact analysis (later in this document). To reach this total, we add one to the total for each pinniped or delphinid that may be captured in longline or gillnet gear, one to the total for each delphinid that may be captured in trawl gear, and one pinniped that may be captured in fyke net gear. This represents the potential that the take of an unidentified pinniped or delphinid could accrue to any given stock captured in that gear. The proposed take authorization is formulated as a five-year total; the annual average is used only for purposes of negligible impact analysis. We recognize that portions of an animal may not be taken in a given year.

[3] See Table 3 and following discussion for more detail regarding PBR.

[4] Estimated maximum annual M/SI + Level A expressed as a percentage of PBR.

[5] See relevant SARs for more information regarding stock status and trends. Interannual increases may not be interpreted as evidence of a trend.

* * * * * * *

2 . On page 46941, in the center column, in the amendatory text for § 219.33, remove ''(Z) Northern bottlenose whale (Hyperoodon ampullatus)—10;'' and add ''(Z) Northern bottlenose whale (Hyperoodon ampullatus)—12;'' in its place.

Dated: August 11, 2015.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–20302 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 80, No. 158
Monday, August 17, 2015

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: Proposed Collection; Comment Request—Food Program and Reporting System (FPRS)

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 a proposed information collection, which is a revision of a currently approved form.

The purpose of the Food Programs Reporting System (FPRS) is to facilitate data gathering for the reporting of data for the Supplemental Nutrition Assistance Program (SNAP) and the Special Nutrition Programs. FPRS consolidated certain programmatic and financial data reporting requirements in an electronic reporting system and is the primary collection point for FNS program performance statistics and financial data from State agencies, Indian Tribal Organizations and U.S. Territories participating in the nutrition assistance programs.

DATES: Written comments must be submitted on or before October 16, 2015.

ADDRESSES: 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 has practical utility; (b) the accuracy of the agency's estimate of the burden hours, 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 through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Comments may be sent to Jane Duffield, Chief, State Administration Branch, Program Accountability and Administration Division, Supplemental Nutrition Assistance Program, U.S. Department of Agriculture, Food and Nutrition Service, 3101 Park Center Drive, Room 818, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Jane Duffield at 703–605–0795, Room 824, or via email to *SNAP-Ed@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 written comments will be open for public inspection at the office of FNS during regular business hours (8:30 a.m. to 5:00 p.m. Monday through Friday) at 3101 Park Center Drive, Room 808, Alexandria, Virginia 22302.

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

CONTACT FOR FURTHER INFORMATION: Requests for additional information should be directed to Usha Kalro at *SNAP-Ed@fns.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Food Programs Reporting System.

OMB Number: 0584–0594.

Form Number and Name: Worksheet FNS–759 Education and Administrative Reporting System.

Expiration Date: 08/31/2016.

Type of Request: Revision of a currently approved information collection.

Abstract: The purpose of the Education and Administrative Reporting System (EARS) maintained in FPRS is to collect uniform and standard information on nutrition education activities funded through the Supplemental Nutrition Assistance Program—Education (SNAP-Ed) program. The data collected through EARS informs management decisions, supports policy initiatives, and provides documentation for legislative, budget, and other requests that support planning within the agency. FNS intends to update the EARS form so that it reflects changes, specifically those that are a direct result of provisions in the Healthy, Hunger-Free Kids Act (HHFKA) of 2010. In addition, FNS continues to explore other ways to improve upon or incorporate metrics that will enhance the evaluation of SNAP-Ed programs. FNS developed EARS for SNAP's nutrition education component, SNAP-Ed, which is provided for in Section 11 of the Food and Nutrition Act (FNA) 2008 (7 U.S.C. 2020 (f)(3)(B)(ii)). In 2003, the Agency convened a workgroup of diverse stakeholders to assist with this task, including people from the Federal, State, and local levels, as well as academia.

The EARS form (FNS–759) was approved by OMB in Fiscal Year (FY) 2007. FNS implemented the first phase of EARS in FY 2008, which required SNAP State agencies to report on financial items only. Full implementation of EARS reporting requirements was completed in FY 2010. EARS provides uniform data and information about the nutrition education activities of all participating States across the country, including the District of Columbia, the Virgin Islands and Guam. Data gathered through the EARS form includes demographic characteristics of participants receiving nutrition education benefits, information about education topics and strategies, and use of resources. The EARS form is designed as an annual report that SNAP State agencies submit using FNS' web-based Food Program Reporting System, OMB Control No: 0584–0594, Expiration Date 6/30/2017. State agencies submit data between October 15 and December 30 of each year for the prior FY's nutrition education activities.

In 2010, Congress passed the HHFKA. Section 241 of the HHFKA replaced the existing nutrition education program under Section 11(f) of the Food and Nutrition Act (''FNS'' or the ''Act'') (7 U.S.C. 2011 *et seq.*) with the nutrition education and obesity prevention grant program under Section 28. FNS continues to refer to the redesigned program as SNAP-Ed. Changes to the program mandated by the HHFKA require revisions to the currently approved EARS form/worksheet. Some of the major changes to SNAP-Ed are:

(1) A focus on the critical problem of obesity—The program now has a wider range of evidence-based intervention strategies. Specifically, SNAP-Ed includes any combination of educational strategies, accompanied by environmental supports, designed to facilitate the voluntary adoption of healthy food and physical activity choices, as well as other nutrition-related behaviors. It is conducive to the well-being of SNAP participants and other qualifying low-income individuals and may involve programs at complementary organizational and institutional levels in addition to community and public health approaches.

(2) A target population which more closely aligns SNAP-Ed participants with those in other FNS, Federal, and State-administered benefit programs. In the past, SNAP-Ed participants included those receiving SNAP or those eligible to receive SNAP. Following the implementation of the HHFKA, the target population is extended to individuals who are eligible to receive SNAP or other means-tested Federal assistance programs or those residing in a community with a significant low-income population. These means-tested programs include Medicaid and Temporary Assistance for Needy Families, among others.

(3) Requirement for evidence-based interventions—Evidence-based approaches have been defined by the FNS Administrator in consultation with the Director of the Centers for Disease Control and Prevention. FNS has provided States with more flexibility by permitting States to use funds for nutrition education and obesity prevention interventions that are developed by integrating the best available research evidence, practice-based evidence or emerging evidence. In accordance with the SNAP-Ed Guidance, these may include the implementation and measurement of policy, systems and environmental changes (PSEs). Expanding the types of environmental and policy approaches that can be used in SNAP-Ed allows State programs to build upon nutrition education and health promotion efforts in a way that better supports a more comprehensive focus on obesity prevention.

(4) A new funding mechanism—As opposed to matching State funds for SNAP-Ed programs, FNS allocates 100 percent Federal grant funding to States, which may coordinate SNAP-Ed activities through partnerships with public and private entities in order to better leverage their financial resources. The formula proscribed by the HHFKA builds progressively to a 50/50 weighting of SNAP-Ed expenditures to SNAP participation based on the funding from the previous 12-month period ending January 31. For Fiscal Year 2015, 80 percent of the funding was based on expenditures and 10 percent of the funding was based on the State's SNAP participation rate. The 50/50 weighting applies to Fiscal Year 2018 and beyond.

The revised form is available for review with this docket on *www.Regulations.gov,* in Supporting Documents. The proposed modifications to the current EARS form/worksheet include the following, where the items pertain to the proposed draft unless stated otherwise:

- Collect data on the number and percentage of SNAP-Ed eligibles and those reached through Direct Education, Social Marketing and PSE change interventions in a State (Item 1a-e).
- Collect data on the estimated percentage of SNAP-Ed funds expended to reach SNAP-Ed eligibles through the above intervention types (Item 1f).
- Added a statement about the Community Eligibility Provision as a special circumstance for determining SNAP status (Items 2a and 2b).
- Collect data on whether SNAP-Ed participation counts for each age group are actual or estimated values (Items 2a and 2b).
- Collect data on additional settings where education is provided to SNAP-Ed participants (Item 5).
- Collect data on whether Direct Education programs are part of a Social Marketing initiative (Item 6a).
- Collect data on whether Direct Education supports PSEs (Item 6b).
- Collect data on whether direct education programs are part of a social marketing and/or PSE interventions (Item 6a and 6b).
- Removed question 8 on Indirect Education (on the current form) and added the column on ''Source(s) of Data'' to the table ''Description of All Social Marketing Campaigns'' (Item 7).
- Collect data on PSEs (Item 8).
- Collect data focused on classifying partnerships and their role in SNAP-Ed programs (Item 9).
- Removed the last question on funding (Item 9 in the current form) since funds are now 100 percent federal allocations to States according to a specified formula and do not require a State match.

The form has been rearranged to better accommodate the instructions and improve the flow of questions. This revision also reflects an increase in burden estimates. FNS estimates that 53 State agencies will respond once a year for a total of 53 annual responses. The current burden it takes each State agency to respond is 54 burden hours. In the revised data collection instrument, it will take approximately 60 burden hours for each State agency to respond which reflects an increase of six burden hours per State from the last submission. The current burden for this collection is 2,808. FNS calculates the revised total burden for this collection is 3,180 annual burden hours which reflects an increase of 300 burden hours due to program changes and adjustments. There are no recordkeeping requirements imposed by this information collection. As this is a revision to the EARS form within the FPRS system, the total FPRS burden is summarized below.

Affected Public: SNAP State agencies and Business. Respondent Type: Businesses are identified as non-profit organizations serving as implementing partners, such as extension universities, and local program operators.

Estimated Number of Respondents: 3,267.

Number of Responses per Respondent: 7.28191.

Estimated Total Annual Responses: 23,790.

Hours per Response: 3.65157629.

Total Annual Burden Hours (Reporting Only): 86,871.

Dated: August 2, 2015.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2015–20208 Filed 8–14–15; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Gallatin Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Gallatin Resource Advisory Committee (RAC) will meet in Bozeman, Montana. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. Additional RAC information, including the meeting agenda and the meeting summary/minutes can be found at the following Web site: *http://*

www.fs.usda.gov/detail/custergallatin/workingtogether/?cid=stelprdb5304491.

DATES: The meeting will be held October 2, 2015, from 9:00 a.m. to 12:30 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Bozeman Public Library, Large Community Room, 626 East Main Street, Bozeman, Montana.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Custer Gallatin National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Mariah Leuschen-Lonergan, RAC Coordinator, by phone at 406–587–6735 or via email at *mdleuschen@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Review project proposals; and
2. Recommend 2015 project proposals.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 21, 2015, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and time requests for oral comments must be sent to Mariah Leuschen-Lonergan, RAC Coordinator, 10 East Babcock Avenue, Bozeman, Montana 59105; by email to *mdleuschen@fs.fed.us*, or via facsimile to 406–587–6758.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 11, 2015.

Mary C. Erickson,

Forest Supervisor, Custer Gallatin National Forest.

[FR Doc. 2015–20202 Filed 8–14–15; 8:45 am]

BILLING CODE 3411–15–P

BROADCASTING BOARD OF GOVERNORS

Sunshine Act Meeting

DATE AND TIME: Wednesday, August 19, 2015 11 a.m. EDT

PLACE: Broadcasting Board of Governors, Cohen Building, Room 3321, 330 Independence Ave. SW., Washington, DC 20237.

SUBJECT: Notice of Closed Meeting of the Broadcasting Board of Governors.

SUMMARY: The members of the Broadcasting Board of Governors (BBG) will meet in a special session, to be conducted telephonically, to discuss and approve a budget submission for Fiscal Year 2017. According to Office of Management and Budget (OMB) Circular A–11, section 22.1, all agency budgetary materials and data are considered confidential prior to the President submitting a budget to Congress. In accordance with section 22.5 of Circular A–11, the BBG has determined that its meeting should be closed to public observation pursuant to 5 U.S.C. 552b(c)(9)(B). In accordance with the Government in the Sunshine Act and BBG policies, the meeting will be recorded and a transcript of the proceedings, subject to the redaction of information protected by 5 U.S.C. 552b(c)(9)(B), will be made available to the public. The publicly-releasable transcript will be available for download at *www.bbg.gov* within 21 days of the date of the meeting.

Information regarding member votes to close the meeting and expected attendees can also be found on the Agency's public Web site.

CONTACT PERSON FOR MORE INFORMATION: Persons interested in obtaining more information should contact Oanh Tran at (202) 203–4545.

Oanh Tran,

Director of Board Operations.

[FR Doc. 2015–20323 Filed 8–13–15; 4:15 pm]

BILLING CODE 8610–01–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility to Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Commerce.

ACTION: Notice and opportunity for public comment.

Pursuant to Section 251 of the Trade Act 1974, as amended (19 U.S.C. 2341 *et seq.*), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE 8/6/2015 THROUGH 8/11/2015

Firm name	Firm address	Date accepted for investigation	Product(s)
Wiretek, Inc.	48 East Newberry Road, Bloomfield, CT 06002.	8/7/2015	The firm manufactures wires and cables.
The Wahl Company, Inc.	624 South Collard Street, Fort Worth, TX 76103.	8/7/2015	The firm manufactures machines, tools, fixtures, discrete parts and assemblies to order.
Lamjen, Inc.	2254 East 30th Street, Erie, PA 16510.	8/7/2015	The firm manufactures precision machined parts.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Dated: August 11, 2015.

Michael S. DeVillo,

Eligibility Examiner.

[FR Doc. 2015–20194 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–92–2015]

Approval of Expansion of Subzone 92A; VT Halter Marine, Inc.; Pascagoula, Mississippi

On June 19, 2015, the Acting Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Mississippi Coast Foreign Trade Zone, Inc., grantee of FTZ 92, requesting an additional site within Subzone 92A on behalf of VT Halter Marine, Inc., located in Pascagoula, Mississippi. The expanded subzone would be subject to the existing activation limit of FTZ 92.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (80 FR 36506–36507, 06–25–2015). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval.

Pursuant to the authority delegated to the FTZ Board's Executive Secretary (15 CFR Sec. 400.36(f)), the application to expand Subzone 92A is approved, subject to the FTZ Act and the Board's regulations, including section 400.13, and with the overall subzone subject to FTZ 92's 2,000-acre activation limit.

Dated: August 11, 2015.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015–20268 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–117–2015]

Foreign-Trade Zone 38—Spartanburg County, South Carolina; Application for Subzone; Springsteen Logistics, LLC; Rock Hill and Fort Lawn, South Carolina

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the South Carolina State Ports Authority, grantee of FTZ 38, requesting subzone status for the facilities of Springsteen Logistics, LLC, located in Rock Hill and Fort Lawn, South Carolina. 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 FTZ Board (15 CFR part 400). It was formally docketed on August 11, 2015.

The proposed subzone would consist of the following sites: *Site 1* (6.6 acres) 220 West White Street, Rock Hill; *Site 2* (24 acres) 5918 Lancaster Highway, Fort Lawn; and, *Site 3* (42 acres) 5992 Lancaster Highway, Fort Lawn. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 38.

In accordance with the FTZ Board's regulations, Kathleen Boyce 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 FTZ Board's Executive Secretary at the address below. The closing period for their receipt is September 28, 2015. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to October 13, 2015.

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 FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Kathleen Boyce at *Kathleen.Boyce@trade.gov* or (202) 482–1346.

Dated: August 11, 2015.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015–20264 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–52–2015]

Foreign-Trade Zone (FTZ) 37—Orange County, NY; Notification of Proposed Production Activity; Takasago International Corporation (USA); (Fragrance Compounds); Harriman, NY

Takasago International Corporation (USA) (Takasago), an operator of FTZ 37, submitted a notification of proposed production activity to the FTZ Board for its facility located in Harriman, New York. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on August 7, 2015.

Takasago already has authority to produce fragrance compounds within Site 10 of FTZ 37. The current request would add foreign-status materials to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials and components and specific finished products 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 materials used in export production. On its domestic sales, Takasago would be able to choose the duty rate during customs entry procedures that applies to fragrance compounds (duty-free) for the foreign status materials noted below and in the existing scope of authority. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

The components and materials sourced from abroad include: Beeswax abs, myroxide, octacetal, syvertal, hydroxyl ambran, safralene, cresyl iso buty, geranyl butyrate, diisobutyl adipate, allyl amyl glyocolate, jasmodione, auirantiol pure, jasmolactone, octalactone delta, g-undecalactone, methyl dioxolan, okumal, grisalva, iso butyl quinolone, peppermint oil, styrax resoid and crystarome strawberry (duty rate ranges from free to 6.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The

closing period for their receipt is September 28, 2015.

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 FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Kathleen Boyce at *Kathleen.Boyce@trade.gov* or (202) 482–1346.

Dated: August 11, 2015.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015–20269 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Transportation and Related Equipment, Technical Advisory Committee; Notice of Partially Closed Meeting

The Transportation and Related Equipment Technical Advisory Committee will meet on September 2, 2015, 9:30 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to transportation and related equipment or technology.

Agenda

Public Session

1. Welcome and Introductions.
2. Status reports by working group chairs.
3. Public comments and Proposals.

Closed Session

4. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov* no later than August 26, 2015.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on October 2, 2014, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § (10)(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482·2813.

Dated: August 11, 2015.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2015–20179 Filed 8–14–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Technical Advisory Committee; Notice of Partially Closed Meeting

The Materials Technical Advisory Committee will meet on September 3, 2015, 10:00 a.m., Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials and related technology.

Agenda

Open Session

1. Introductions and opening remarks on ECR by senior management.
2. Foreign Policy brief on Cuba.
3. Open session report by on regime representatives.
4. Report from working groups (Composite Working Group, Biological Working Group, Pump and Valves Working Group, and the Chemicals Working Group).
5. Remarks by the Office of Technology Evaluation.
6. Public Comments and New Business.

Closed Session

7. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than August 27, 2015.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the materials should be forwarded prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on March 18, 2015, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 § § 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Dated: August 11, 2015.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2015–20178 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–880, A–201–847, A–489–824]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes From the Republic of Korea, Mexico, and the Republic of Turkey: Initiation of Less-Than-Fair-Value Investigations

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

DATES: *Effective Date:* August 17, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth Eastwood at (202) 482–3874 (the Republic of Korea and Mexico), or Brandon Custard at (202) 482–1823 (the Republic of Turkey), AD/CVD Operations, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On July 21, 2015, the Department of Commerce (the Department) received antidumping duty (AD) petitions concerning imports of heavy walled rectangular carbon steel pipes and tubes (HWR pipes and tubes) from the Republic of Korea (Korea), Mexico, and the Republic of Turkey (Turkey) filed in proper form on behalf of Atlas Tube, a division of JMC Steel Group, Bull Moose Tube Company, EXLTUBE,[1] Hannibal Industries, Inc., Independence Tube Corporation, Maruichi American Corporation, Searing Industries, Southland Tube, and Vest, Inc. (collectively, the petitioners). The AD petitions were accompanied by one countervailing duty (CVD) petition also concerning imports of HWR pipes and tubes from Turkey.[2] The petitioners are domestic producers of HWR pipes and tubes.[3]

On July 23, 2015, the Department requested additional information and clarification of certain areas of the Petitions.[4] The petitioners filed responses to these requests on July 24 and 27, 2015.[5]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioners allege that imports of HWR pipes and tubes from Korea, Mexico, and Turkey are being, or are likely to be, sold in the United States at less-than-fair value within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 732(b)(1) of the Act, the Petitions are accompanied by information reasonably available to the petitioners supporting their allegations.

The Department finds that the petitioners filed these Petitions on behalf of the domestic industry because the petitioners are interested parties as defined in section 771(9)(C) of the Act. The Department also finds that the petitioners demonstrated sufficient industry support with respect to the initiation of the AD investigations that the petitioners are requesting.[6]

Period of Investigation

Because the Petitions were filed on July 21, 2015, pursuant to 19 CFR 351.204(b)(1) the period of investigation (POI) is July 1, 2014, through June 30, 2015.

Scope of the Investigations

The product covered by these investigations is HWR pipes and tubes from Korea, Mexico, and Turkey. For a full description of the scope of these investigations, see the ''Scope of the Investigations,'' in Appendix I of this notice.

Comments on Scope of the Investigations

During our review of the Petitions, the Department issued questions to, and received responses from, the petitioners pertaining to the proposed scope to ensure that the scope language in the Petitions would be an accurate reflection of the products for which the domestic industry is seeking relief.[7]

As discussed in the preamble to the Department's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope). The Department will consider all comments received from parties and, if necessary, will consult with parties prior to the issuance of the preliminary determinations. If scope comments include factual information (*see* 19 CFR 351.102(b)(21)), all such factual information should be limited to public information. In order to facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Time (ET) on Monday, August 31, 2015, which is the first business day after 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on Thursday, September 10, 2015, which is 10 calendar days after the initial comments deadline.

The Department requests that any factual information the parties consider relevant to the scope of the investigations be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact the Department and request permission to submit the additional information. All such comments must be filed on the records of each of the concurrent AD and CVD investigations.

Filing Requirements

Submissions to the Department must normally be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[8] An electronically filed document must be received successfully in its entirety by the time and date when it is due. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce,

[1] EXLTUBE is not a petitioner in the AD petition concerning imports of HWR pipes and tubes from Mexico.

[2] *See* Petitions for the Imposition of Antidumping and Countervailing Duties: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Korea, Mexico, and Turkey, dated July 21, 2015 (the Petitions).

[3] *See* Volume I of the Petitions, at 2.

[4] *See* Letter from the Department to Petitioners entitled ''Re: Petitions for the Imposition of Antidumping Duties on Imports of Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey and Countervailing Duties on Imports of Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey: Supplemental Questions,'' dated July 23, 2015; Letter from the Department to Petitioners entitled ''Re: Petition for the Imposition of Antidumping Duties on Imports of Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Korea: Supplemental Questions,'' dated July 23, 2015; Letter from the Department to Petitioners entitled ''Re: Petition for the Imposition of Antidumping Duties on Imports of Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Supplemental Questions,'' dated July 23, 2015; and Letter from the Department to Petitioners entitled ''Re: Petition for the Imposition of Antidumping Duties on Imports of Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey: Supplemental Questions,'' dated July 23, 2015. (collectively, General Issues Supplemental Questionnaire).

[5] *See* Letters from the petitioners entitled, ''Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Korea,'' ''Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico,'' and ''Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Turkey,'' dated July 24, 2015; Response to the Department's July 23, 2015, Supplemental Questionnaire Regarding Volume I of the Petitions for the Antidumping and Countervailing Duties, dated July 27, 2015 (General Issues Supplement); and Response to the Department's July 23, 2015, Supplemental Questionnaires Regarding Volumes II, III, and IV of the Petitions for the Imposition of Antidumping and Countervailing Duties, dated July 27, 2015.

[6] *See* the ''Determination of Industry Support for the Petitions'' section below.

[7] *See* General Issues Supplemental Questionnaire; *see also* General Issues Supplement.

[8] *See* 19 CFR 351.303 (for general filing requirements); *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011) for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Comments on Product Characteristics for AD Questionnaires

The Department requests comments from interested parties regarding the appropriate physical characteristics of HWR pipes and tubes to be reported in response to the Department's AD questionnaires. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant factors and costs of production accurately as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics and (2) product-comparison criteria. We note that it is not always appropriate to use all product characteristics as product-comparison criteria. We base product-comparison criteria on meaningful commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe HWR pipes and tubes, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, the Department attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all comments must be filed by 5:00 p.m. ET on Monday, August 31, 2015, which is 21 calendar days from the signature date of this notice. Any rebuttal comments must be filed by 5:00 p.m. ET on Thursday, September 10, 2015. All comments and submissions to the Department must be filed electronically using ACCESS, as explained above, on the records of the Korea, Mexico, and Turkey less-than-fair-value investigations.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[9] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[10]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the Petitions).

With regard to the domestic like product, the petitioners do not offer a definition of the domestic like product distinct from the scope of the investigations. Based on our analysis of the information submitted on the record, we have determined that HWR pipes and tubes, as defined in the scope of the investigations, constitute a single domestic like product and we have analyzed industry support in terms of that domestic like product.[11]

In determining whether the petitioners have standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of the Investigations,'' in Appendix I of this notice. To establish industry support, the petitioners provided their own shipments of the domestic like product in 2014 and compared their shipments to the estimated total shipments of the domestic like product for the entire domestic industry.[12] Because data regarding total production of the domestic like product for 2014 are not reasonably available to the petitioners and the petitioners have established that shipments are a reasonable proxy for production,[13] we relied on the shipment data provided by the petitioners for purposes of measuring industry support.[14] We note that EXLTUBE is not a petitioner with respect to the petition for the imposition of antidumping duties on imports of HWR pipes and tubes from Mexico and has not expressed an opinion with regard to the petition on imports from Mexico.

[9] *See* section 771(10) of the Act.

[10] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[11] For a discussion of the domestic like product analysis in this case, *see* Antidumping Duty Investigation Initiation Checklist: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea (Korea Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey (Attachment II); Antidumping Duty Investigation Initiation Checklist: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico (Mexico Initiation Checklist), at Attachment II; and Antidumping Duty Investigation Initiation Checklist: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey (Turkey AD Initiation Checklist), at Attachment II. These checklists are dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[12] *See* Volume I of the Petitions, at 3–4 and Exhibits I–1 and I–2; *see also* General Issues Supplement, at 4–5 and Exhibit I–10.

[13] *See* Volume I of the Petitions, at 3–4; *see also* General Issues Supplement, at 4.

[14] For further discussion, *see* Korea Initiation Checklist, Mexico Initiation Checklist, and Turkey AD Initiation Checklist, at Attachment II.

Therefore, we have not included shipments from EXLTUBE to measure industry support for the Mexico Petition.[15]

Our review of the data provided in the Petitions, General Issues Supplement, and other information readily available to the Department indicates that the petitioners have established industry support for all of the Petitions.[16] First, the Petitions established support from domestic producers (or workers) accounting for more than 50 percent of the total shipments [17] of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.,* polling).[18] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act for all of the Petitions because the domestic producers (or workers) who support each of the Petitions account for at least 25 percent of the total shipments of the domestic like product.[19] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act for all of the Petitions because the domestic producers (or workers) who support each of the Petitions account for more than 50 percent of the shipments of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions.[20] Accordingly, the Department determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

The Department finds that the petitioners filed the Petitions on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act and they have demonstrated sufficient industry support with respect to the AD investigations that they are requesting the Department initiate.[21]

[15] *See* Volume I of the Petitions, at 1.

[16] *See* Korea Initiation Checklist, Mexico Initiation Checklist, and Turkey AD Initiation Checklist, at Attachment II.

[17] As mentioned above, the petitioners established that shipments are a reasonable proxy for production data. Section 351.203(e)(1) of the Department's regulations states ''production levels may be established by reference to alternative data that the Secretary determines to be indicative of production levels.''

[18] *See* section 732(c)(4)(D) of the Act; *see also* Korea Initiation Checklist, Mexico Initiation Checklist, and Turkey AD Initiation Checklist, at Attachment II.

[19] *See* Korea Initiation Checklist, Mexico Initiation Checklist, and Turkey AD Initiation Checklist, at Attachment II.

[20] *Id.*

[21] *Id.*

Allegations and Evidence of Material Injury and Causation

The petitioners allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at less than normal value (NV). In addition, the petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[22]

The petitioners contend that the industry's injured condition is illustrated by reduced market share; underselling and price depression or suppression; lost sales and revenues; increased inventories and inventory overhang in the U.S. market; and decline in profitability.[23] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation.[24]

Allegations of Sales at Less-Than-Fair Value

The following is a description of the allegations of sales at less-than-fair value upon which the Department based its decision to initiate investigations of imports of HWR pipes and tubes from Korea, Mexico, and Turkey. The sources of data for the deductions and adjustments relating to U.S. price and NV are discussed in greater detail in the country-specific initiation checklists.

Export Price

For Korea, Mexico, and Turkey, the petitioners based U.S. price on price quotes/offers for sales of HWR pipes and tubes produced in, and exported from, the subject country.[25] The petitioners made deductions from U.S. price for movement expenses consistent with the delivery terms.[26] Where applicable, the petitioners also deducted from U.S. price trading company mark-ups estimated using the petitioners' knowledge of the U.S. industry.[27]

Normal Value

For Korea, Mexico, and Turkey, the petitioners provided home market price information obtained through market research for HWR pipes and tubes produced and offered for sale in each of these countries.[28] For each country, the petitioners provided an affidavit or declaration from a market researcher for the price information.[29] The petitioners made no adjustments to these prices consistent with the terms of sale.

Fair Value Comparisons

Based on the data provided by the petitioners, there is reason to believe that imports of HWR pipes and tubes from Korea, Mexico, and Turkey are being, or are likely to be, sold in the United States at less-than-fair value. Based on comparisons of export price to NV in accordance with section 773(a) of the Act, the estimated dumping margin for HWR pipes and tubes from Korea is 53.8 percent.[30] The estimated dumping margin for Mexico is 11.9 percent.[31] The estimated dumping margins for Turkey range from 102.1 to 113.7 percent.[32]

Initiation of Less-Than-Fair-Value Investigations

Based upon the examination of the AD Petitions on HWR pipes and tubes from Korea, Mexico, and Turkey, we find that Petitions meet the requirements of section 732 of the Act. Therefore, we are initiating AD investigations to determine whether imports of HWR pipes and tubes from Korea, Mexico and Turkey, are being, or are likely to be, sold in the United States at less-than-fair value. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Respondent Selection

The petitioners named ten companies from Korea, ten companies from Mexico, and 14 companies from Turkey as producers/exporters of HWR pipes and tubes.[33] Following standard practice in AD investigations involving market economy countries, the

[22] *See* General Issues Supplement, at 5 and Exhibit I–13.

[23] *See* Volume I of the Petitions, at 9–10, 12–27 and Exhibits I–1, I–5, I–7 and I–8; *see also* General Issues Supplement, at 1, 5 and Exhibits I–12 and I–13.

[24] *See* Korea Initiation Checklist, Mexico Initiation Checklist, and Turkey AD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey.

[25] *See* Korea Initiation Checklist; Mexico Initiation Checklist; and Turkey AD Initiation Checklist.

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.*; *see also* Memoranda to the File, ''Telephone Call to Foreign Market Researcher Regarding Antidumping Duty Petition,'' on each of the country-specific records, dated July 31, 2015.

[30] *See* Korea Initiation Checklist.

[31] *See* Mexico Initiation Checklist.

[32] *See* Turkey AD Initiation Checklist.

[33] *See* Volume I of the Petitions, at Exhibit I–4.

Department intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the POI under Harmonized Tariff Schedule of the United States (HTSUS) number 7306.61.1000.[34] We intend to release the CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO within five days of publication of this **Federal Register** notice and make our decision regarding respondent selection within 20 days of publication of this notice.

We invite interested parties to comment on this issue. Parties wishing to comment must do so within seven days of the publication of this notice in the **Federal Register**. Comments must be filed electronically using ACCESS. An electronically-filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5 p.m. ET by the deadline noted above.

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to the governments of Korea, Mexico, and Turkey via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petitions to each exporter named in the Petitions, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We have notified the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of HWR pipes and tubes from Korea, Mexico, and/or Turkey are materially injuring or threatening material injury to a U.S. industry.[35] A negative ITC determination for any country will result in the investigation being terminated with respect to that country; [36] otherwise, these investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The regulation requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Please review the regulations prior to submitting factual information in these investigations.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under part 351, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under part 351 expires. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these investigations.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[37] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[38] The Department intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed in 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 732 and 777(i) of the Act.

Dated: August 10, 2015.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigations

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

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

[34] While the scope also references HTSUS number 7306.61.3000, we note that this HTSUS number includes non-subject merchandise. Therefore, we do not intend to use data for this HTSUS number for purposes of respondent selection.

[35] *See* section 733(a) of the Act.

[36] *Id.*

[37] *See* section 782(b) of the Act.

[38] *See Certification of Factual Information to Import Administration during Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

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

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

[FR Doc. 2015–20271 Filed 8–14–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–825]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes From the Republic of Turkey: Initiation of Countervailing Duty Investigation

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

DATES: *Effective Date:* August 17, 2015.

FOR FURTHER INFORMATION CONTACT: Rebecca Trainor at (202) 482–4007 or Reza Karamloo at (202) 482–4470, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On July 21, 2015, the Department of Commerce (the Department) received a countervailing duty (CVD) petition concerning imports of heavy walled rectangular welded carbon steel pipes and tubes (HRW pipes and tubes) from the Republic of Turkey (Turkey), filed in proper form, on behalf of Atlas Tube, a division of JMC Steel Group, Bull Moose Tube Company, EXLTUBE, Hannibal Industries, Inc., Independence Tube Corporation, Maruichi American Corporation, Searing Industries, Southland Tube, and Vest, Inc. (collectively, the petitioners).[1] The CVD Petition was accompanied by antidumping duty (AD) petitions with respect to Turkey, the Republic of Korea (Korea), and Mexico. The petitioners are domestic producers of HWR pipes and tubes.[2]

On July 23, 2015, the Department requested information and clarification for certain areas of the Petition.[3] The petitioners filed responses to these requests on July 27, 2015.[4]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioners allege that the Government of Turkey (GOT) is providing countervailable subsidies (within the meaning of sections 701 and 771(5) of the Act) to imports of HWR pipes and tubes from Turkey, and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 702(b)(1) of the Act, the Petition is accompanied by information reasonably available to the petitioners supporting their allegations.

The Department finds that the petitioners filed the Petition on behalf of the domestic industry because the petitioners are interested parties as defined in section 771(9)(C) of the Act. The Department also finds that the petitioners demonstrated sufficient industry support with respect to the initiation of the CVD investigation that the petitioners are requesting.[5]

Period of Investigation

The period of the investigation is January 1, 2014, through December 31, 2014.[6]

Scope of the Investigation

The product covered by this investigation is HWR pipes and tubes from Turkey. For a full description of the scope of this investigation, *see* the ''Scope of the Investigations'' in Appendix I of this notice.

Comments on Scope of the Investigations

During our review of the Petition, the Department issued questions to, and received responses from, the petitioners pertaining to the proposed scope to ensure that the scope language in the Petition would be an accurate reflection of the products for which the domestic industry is seeking relief.[7]

As discussed in the preamble to the Department's regulations,[8] we are setting aside a period for interested parties to raise issues regarding product coverage (scope). The Department will consider all comments received from parties and, if necessary, will consult with parties prior to the issuance of the preliminary determination. If scope comments include factual information (*see* 19 CFR 351.102(b)(21)), all such factual information should be limited to public information. In order to facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Time (ET) on August 31, 2015, which is the first business day after 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on September 10, 2015, which is 10 calendar days after the initial comments deadline.

The Department requests that any factual information the parties consider relevant to the scope of the investigations be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact the Department and request permission to submit the additional information. All such comments must be filed on the records of the Turkey AD and CVD investigations, as well as the concurrent Korea and Mexico AD investigations.

Filing Requirements

Submissions to the Department normally must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty

[1] *See* Petitions for the Imposition of Antidumping and Countervailing Duties: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes, dated July 21, 2015, at Volume V (CVD Petition or Petition).

[2] *See* Volume I of the Petitions, at 1.

[3] *See* Letter from the Department to the petitioners, ''Petitions for the Imposition of Antidumping Duties on Imports of Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey and Countervailing Duties on Imports of Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey: Supplemental Questions,'' (July 23, 2015) (General Issues Supplemental Questionnaire), and Letter from the Department to the petitioners ''Petition for the Imposition of Countervailing Duties on Imports of Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey: Supplemental Question,'' (July 23, 2015) (CVD Supplemental Questionnaire).

[4] *See* ''Responses To Supplemental Questions Regarding The Petitions for the Imposition of Antidumping and Countervailing Duties: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes,'' (July 27, 2015), (General Issues Supplement), and ''Response To Supplemental Question Regarding The Petition Against Turkey for the Imposition of Countervailing Duties: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes,'' (July 27, 2015) (CVD Supplement).

[5] *See* the ''Determination of Industry Support for the Petitions'' section below.

[6] 19 CFR 351.204(b)(2).

[7] *See* General Issues Supplemental Questionnaire; *see also* General Issues Supplement.

[8] *See Antidumping Duties; Countervailing Duties; Final rule,* 62 FR 27296, 27323 (May 19, 1997).

Centralized Electronic Service System (ACCESS).[9] An electronically-filed document must be received successfully in its entirety by the time and date it is due. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Consultations

Pursuant to section 702(b)(4)(A)(i) of the Act, the Department notified representatives of the GOT of the receipt of the Petition. Also, in accordance with section 702(b)(4)(A)(ii) of the Act, the Department provided representatives of the GOT the opportunity for consultations with respect to the Petition.[10] Consultations were held with the GOT on August 6, 2015.[11] The memorandum regarding these consultations is on file electronically via ACCESS.[12]

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the Petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the Petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[13] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[14]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the Petition).

With regard to the domestic like product, the petitioners do not offer a definition of the domestic like product distinct from the scope of the investigation. Based on our analysis of the information submitted on the record, we have determined that HWR pipes and tubes, as defined in the scope of the investigation, constitute a single domestic like product and we have analyzed industry support in terms of that domestic like product.[15]

In determining whether the petitioners have standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in Appendix I of this notice. To establish industry support, the petitioners provided their own shipments of the domestic like product in 2014 and compared their shipments to estimated total shipments of the domestic like product for the entire domestic industry.[16] Because data regarding total production of the domestic like product are not reasonably available to the petitioners and the petitioners have established that shipments are a reasonable proxy for production,[17] we have relied on the shipment data provided by the petitioners for purposes of measuring industry support.[18]

Our review of the data provided in the Petition, General Issues Supplement, and other information readily available to the Department indicates that the petitioners have established industry support for the Petition.[19] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total shipments [20] of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.*, polling).[21] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act for the Petition because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total shipments of the domestic like

[9] *See* 19 CFR 351.303 (for general filing requirements); *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011), for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

[10] *See* Letter of invitation from the Department to the GOT, dated July 27, 2015.

[11] *See* Memorandum to the File, ''Consultations with Officials from the Government of the Republic of Turkey Regarding the Countervailing Duty Petition Concerning Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes,'' dated August 6, 2015.

[12] *See supra* note 9 for information pertaining to ACCESS.

[13] *See* section 771(10) of the Act.

[14] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[15] For a discussion of the domestic like product analysis in this case, *see* Countervailing Duty Investigation Initiation Checklist: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey (Turkey CVD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey (Attachment II). This checklist is dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[16] *See* Volume I of the Petition, at 3–4 and Exhibits I–1 and I–2; *see also* General Issues Supplement, at 4–5 and Exhibit I–10.

[17] *See* Volume I of the Petition, at 3–4; *see also* General Issues Supplement, at 4.

[18] For further discussion, *see* Turkey CVD Initiation Checklist, at Attachment II.

[19] *See* Turkey CVD Initiation Checklist, at Attachment II.

[20] As mentioned above, the petitioners have established that shipments are a reasonable proxy for production data. Section 351.203(e)(1) of the Department's regulations states ''production levels may be established by reference to alternative data that the Secretary determines to be indicative of production levels.''

[21] *See* section 702(c)(4)(D) of the Act; *see also* Turkey CVD Initiation Checklist, at Attachment II.

product.[22] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act for the Petition because the domestic producers (or workers) who support the Petition account for more than 50 percent of the shipments of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[23] Accordingly, the Department determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.

The Department finds that the petitioners filed the Petition on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act and they have demonstrated sufficient industry support with respect to the CVD investigation that they are requesting the Department initiate.[24]

Injury Test

Because Turkey is a ''Subsidies Agreement Country'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from Turkey materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioners allege that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. The petitioners allege that subject imports exceed the negligibility threshold of three percent provided for under section 771(24)(A) of the Act.[25]

The petitioners contend that the industry's injured condition is illustrated by reduced market share; underselling and price suppression or depression; lost sales and revenues; increased inventories and inventory overhang in the U.S. market; and decline in profitability.[26] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation.[27]

Initiation of Countervailing Duty Investigations

Section 702(b)(1) of the Act requires the Department to initiate a CVD investigation whenever an interested party files a CVD Petition on behalf of an industry that: (1) Alleges the elements necessary for an imposition of a duty under section 701(a) of the Act; and (2) is accompanied by information reasonably available to the petitioner supporting the allegations.

The petitioners allege that producers/exporters of HWR pipes and tubes in Turkey benefited from countervailable subsidies bestowed by the government. The Department has examined the Petition and finds that it complies with the requirements of section 702(b)(1) of the Act. Therefore, in accordance with section 702(b)(1) of the Act, we are initiating a CVD investigation to determine whether manufacturers, producers, or exporters of HWR pipes and tubes from Turkey receive countervailable subsidies from the government.

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation on each of the alleged programs. For a full discussion of the basis for our decision to initiate on each program, *see* CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 65 days after the date of this initiation.

Respondent Selection

The petitioners named 14 companies as producers/exporters of heavy walled rectangular welded carbon steel pipes and tubes from Turkey.[28] Following standard practice in CVD investigations, the Department will, where appropriate, select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports of HWR pipes and tubes during the period of investigation under Harmonized Tariff Schedule of the United States (HTSUS) number 7306.61.1000.[29] We intend to release CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO within five days of publication of this **Federal Register** notice. The Department invites comments regarding respondent selection within seven days of publication of this **Federal Register** notice.

Comments must be filed electronically using ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS, by 5 p.m. ET by the date noted above. We intend to make our decision regarding respondent selection within 20 days of publication of this notice. Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Department's Web site at *http://enforcement.trade.gov/apo*.

Distribution of Copies of the Petition

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the GOT via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to each known exporter (as named in the Petition), consistent with 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determination by the ITC

Within 45 days after the date on which the Petition was filed, the ITC will preliminarily determine whether there is a reasonable indication that imports of HWR pipes and tubes from Turkey are materially injuring, or threatening material injury to, a U.S. industry.[30] A negative ITC determination will result in the investigation being terminated; [31] otherwise, this investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires;

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *See* General Issues Supplement, at 5 and Exhibit I–13.

[26] *See* Volume I of the Petition, at 9–10, 12–27 and Exhibits I–1, I–5, I–7 and I–8; *see also* General Issues Supplement, at 1, 5 and Exhibits I–12 and I–13.

[27] *See* Turkey CVD Initiation Checklist at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey.

[28] *See* Volume I of the Petitions, at Exhibit I–4.

[29] While the scope also references HTSUS number 7306.61.3000, we note that this HTSUS number includes non-subject merchandise. Therefore, we do not intend to use data for this HTSUS number for purposes of respondent selection.

[30] *See* section 703(a) of the Act.

[31] *Id.*

(ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The regulation requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Parties should review the regulations prior to submitting factual information in this investigation.

Extension of Time Limits Regulation

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the time limit established under 19 CFR 351.301 expires. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in this investigation.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[32] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule*.[33] The Department intends to reject factual submissions if the submitting party does not comply with the applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 702 and 777(i) of the Act.

Dated: August 10, 2015.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

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

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

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

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

[FR Doc. 2015–20270 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–DS–P

[32] *See* section 782(b) of the Act.

[33] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC554

Marine Mammals; File No. 17952

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

ACTION: Notice; receipt of application for permit amendment.

SUMMARY: Notice is hereby given that Daniel P. Costa, Ph.D., Department of Biology and Institute of Marine Sciences, University of California, Santa Cruz, CA 95064, has applied for an amendment to Scientific Research Permit No. 17952–01.

DATES: Written, telefaxed, or email comments must be received on or before September 16, 2015.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 17952 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301)

713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 17952 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Amy Sloan or Brendan Hurley, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject amendment to Permit No. 17952–01 is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Permit No. 17952, issued on June 11, 2013 (78 FR 37796), authorizes the permit holder to conduct long-term research on California sea lions (*Zalophus californianus*) studying their foraging, diving, energetics, food habits, and at sea distribution. Dr. Costa is authorized to capture, sample, and tag California sea lions and recapture tagged California sea lions throughout their U.S. range (California, Oregon and Washington). Harassment of California sea lions, harbor seals (*Phoca vitulina*), and northern elephant seals (*Mirounga angustirostris*) incidental to research activities, unintentional mortalities of California sea lions, and import and export of pinniped samples is authorized. The permit was amended via a minor amendment (Permit No. 17952–01) on October 22, 2014, to include attachment of cameras to instrumentation deployed on sea lions already permitted for capture, sampling, and instrumentation, and to include intubation during gas anesthesia. The permit expires June 7, 2018.

The permit holder is requesting the permit be amended to include authorization to (1) add remote darting as an approved capture method with use of various sedative drugs for adult and juvenile California sea lions, (2) increase incidental harassment takes of non-target California sea lions, (3) include incidental harassment takes for the Eastern stock of Steller sea lions (*Eumetopias jubatus*), and (4) include takes for capture and disentanglement of California sea lions. The proposed takes are delineated in the amendment application and are requested for the duration of the permit.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: August 12, 2015.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–20209 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE074

Atlantic Highly Migratory Species; Meeting of the Atlantic Highly Migratory Species Advisory Panel; Correction

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

ACTION: Notice of public meeting and webinar/conference call; correction.

SUMMARY: This document corrects the **ADDRESSES** section to the Notice of public meeting and webinar/conference call that was published on August 5, 2015, which did not contain all of the necessary information for those interested in participating in the webinar/conference call portion of the Atlantic Highly Migratory Species (HMS) Advisory Panel (AP) meeting in September 2015. This correction changes the webinar event addresses, conference call-in number, and participant codes.

DATES: The HMS AP meeting and webinar will be held from 9 a.m. to 6 p.m. on Wednesday, September 9, 2015; and from 8:30 a.m. to 12 p.m. on Thursday, September 10, 2015.

ADDRESSES: The meeting will be held at the Sheraton Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910. The meeting presentations will also be available via WebEx webinar/conference call.

On Wednesday, September 9, 2015, the conference call information is: phone number 1–866–509–5013; Participant Code: 1475429; and the webinar event address is: *https://noaaevents2.webex.com/noaaevents2/onstage/g.php?d=999136478&t=a; event password: NOAA.*

On Thursday, September 10, 2015, the conference call information is: Phone number 1–866–509–5013; Participant Code: 1475429; and the webinar event address is: *https://noaaevents2.webex.com/noaaevents2/onstage/g.php?d=995421572&t=a;* event password: NOAA.

Participants are strongly encouraged to log/dial in fifteen minutes prior to the meeting. NMFS will show the presentations via webinar and allow public comment during identified times on the agenda.

FOR FURTHER INFORMATION CONTACT: LeAnn Hogan or Margo Schulze-Haugen at (301) 427–8503.

SUPPLEMENTARY INFORMATION:

Need for Correction

The original notice (80 FR 46544) didn't contain all of the necessary information in the **ADDRESSES** section. This document corrects the **ADDRESSES** section so that all interested parties have the necessary information pertaining to the webinar event addresses, conference call-in number, and participant codes.

In addition, we've included the new **ADDRESSES** section above, for clarity.

Correction

In a Notice published on August 5, 2015 (80 FR 46544), on page 46545, please make the following correction: In the first column, in the second and third paragraphs under the **ADDRESSES** heading, the WebEx webinar/conference call information is corrected to read as follows:

''On Wednesday, September 9, 2015, the conference call information is: phone number 1–866–509–5013; Participant Code: 1475429; and the webinar event address is: *https://noaaevents2.webex.com/noaaevents2/onstage/g.php?d=999136478&t=a; event password: NOAA.*

On Thursday, September 10, 2015, the conference call information is: Phone number 1–866–509–5013; Participant Code: 1475429; and the webinar event address is: *https://noaaevents2.webex.com/noaaevents2/onstage/g.php?d=995421572&t=a;* event password: NOAA.''

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

Dated: August 12, 2015.

Alan D. Risenhoover,

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

[FR Doc. 2015–20222 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE115

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting (webinar).

SUMMARY: The Pacific Fishery Management Council (Pacific Council) will convene a joint webinar meeting of its Coastal Pelagic Species Management Team (CPSMT) and Coastal Pelagic Species Advisory Subpanel (CSPAS). The meeting is open to the public.

DATES: The webinar meeting will be held Thursday, September 3, 2015, from 1 p.m. to 3 p.m. Pacific Daylight Time.

ADDRESSES: To attend the webinar, visit: *http://www.gotomeeting.com/online/webinar/join-webinar.* Enter the Webinar ID, which is 104-871-531, and your name and email address (required). Participants are encouraged to use their telephone, as this is the best practice to avoid technical issues and excessive feedback (see the *PFMC GoToMeeting Audio Diagram* for best practices). Please use your telephone for the audio portion of the meeting by dialing this TOLL number 1+951–384–3421 (not a toll-free number); then enter the Attendee phone audio access code: 468-846-695; then enter your audio phone pin (shown after joining the webinar). System Requirements for PC-based attendees: Required: Windows® 7, Vista, or XP; for Mac®-based attendees: Required: Mac OS® X 10.5 or newer; and for mobile attendees: iPhone®, iPad®, Android™ phone or Android tablet (See the GoToMeeting Webinar Apps).

You may send an email to *Mr. Kris Kleinschmidt* or contact him at (503) 820–2280, extension 425 for technical assistance. A public listening station will be available at the Pacific Council office.

Council address: Pacific Fishery Management Council, 7700 NE. Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer; telephone: (503) 820–2409.

SUPPLEMENTARY INFORMATION: The primary purpose of the meeting is to discuss agenda items on the September 2015 Pacific Council meeting agenda and to discuss future meeting plans. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the CPSMT and CPSAS' intent to take final action to address the emergency.

Special Accommodations

The public listening station is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (503) 820–2280 at least 5 days prior to the meeting date.

Dated: August 12, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–20207 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE114

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Habitat Committee (HC) will hold a webinar that is open to the public.

DATES: The HC meeting will be held Tuesday, September, 1, 2015, from 1 p.m. until 3 p.m.

ADDRESSES: To attend the webinar, visit: *https://global.gotomeeting.com/join/539285365.* Enter the Webinar ID, which is 539–285–365, and your name and email address (required). Participants are encouraged to use their telephone, as this is the best practice to avoid technical issues and excessive feedback (see the *PFMC GoToMeeting Audio Diagram (http://t.sidekickopen14.com/e1t/c/5/f18dQhb0S7lC8dDMPbW2n0x6l2B9nMJW7t5XYg8pTkCFVfmWRK8qm29WW2zq3QW56dJHNf6V05r202?t=http%3A%2F%2Fwww.pcouncil.org%2Fwp-content%2Fuploads%2FPFMC_Audio_Diagram_GoToMeeting.pdf&si=6706403137290240&pi=3e8f7565-3109-406a-8f2d-c0dfb39dbb8d)* for best practices). Please use your telephone for the audio portion of the meeting by dialing this TOLL number 1+872–240–3212 (not a toll-free number); then enter the Attendee phone audio access code: 539–285–365; then enter your audio phone pin (shown after joining the webinar). System Requirements for PC-based attendees: Required: Windows® 7, Vista, or XP; for Mac®-based attendees: Required: Mac OS® X 10.5 or newer; and for mobile attendees: iPhone®, iPad®, Android™ phone or Android tablet (see the GoToMeeting Webinar Apps).

You may send an email to Mr. Kris Kleinschmidt *(kris.kleinschmidt@noaa.gov)* or contact him at (503) 820–2280, extension 425 for technical assistance. A public listening station will also be provided at the Pacific Council office.

Council address: Pacific Council, 7700 NE. Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Gilden, Pacific Council, (503) 820–2418.

SUPPLEMENTARY INFORMATION: The primary purpose of the HC working meeting is to prepare for the September 2015 Pacific Council meeting, specifically Agenda Item H.8, Amendment to Modify Groundfish Essential Fish Habitat and to Adjust Rockfish Conservation Areas. Public comment will be accommodated if time allows, at the discretion of the HC Chair. The HC's task will be to develop recommendations for consideration by the Pacific Council at its September 9–16, 2015 meeting in Sacramento, CA.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2425 at least 5 days prior to the meeting date.

Dated: August 12, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–20206 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE104

Western Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of a public meeting.

SUMMARY: The Western Pacific Fishery Management Council (Council) will convene a meeting of Habitat Areas of Particular Concern (HAPC) Working Group comprised of Fishery Ecosystem Plan Team members. The working group will plan for producing a report exploring options in developing an HAPC designation process for the Western Pacific region.

DATES: The working group will meet on September 2, 2015. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The HAPC working group meeting will be held at the Council office, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813; telephone: (808) 522–8220. WebEx and teleconference facilities will be provided for the meeting. The teleconference numbers are: U.S. toll-free: 1–888–482–3560 or International Access: +1–647–723–3959, and Access Code: 5228220; The Web conference can be accessed at *https://wprfmc.webex.com/join/info.wpcouncilnoaa.gov*.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: HAPC working group members will explore different process options for designating Habitat Areas of Particular Concern in the Western Pacific Region. The purpose of this meeting is to identify which process options to evaluate in a report to the Council's Fishery Ecosystem Plan Team. A public comment period will be provided. The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the HAPC Working Group Meeting

September 2, 2015—1 p.m.–4 p.m.

1. Introductions
2. Purpose of meeting
3. Overview of Essential Fish Habitat and Habitat Areas of Particular Concern
4. Options From Other Regions
5. Consideration of Additional Options
6. Public Comment
7. Deliberation on Options to Evaluate
8. Other Business

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: August 12, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–20203 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE108

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Salmon Technical Team (STT), Salmon Advisory Subpanel (SAS), and Model Evaluation Workgroup (MEW) will hold a webinar, which is open to the public.

DATES: The webinar will be held on Wednesday, September 2, 2015, from 1:30 p.m. until business for the day is complete.

ADDRESSES: To attend the webinar, visit: *http://www.gotomeeting.com/online/webinar/join-webinar.* Enter the Webinar ID, which is 131–126–235, and your name and email address (required). Participants are encouraged to use their telephone, as this is the best practice to avoid technical issues and excessive feedback. (See the PFMC GoToMeeting Audio Diagram (*http://t.sidekickopen14.com/e1t/c/5/f18dQhb0S7lC8dDMPbW2n0x6l2B9nMJW7t5XYg8pTkCFVfmWRK8qm29WW2zq3QW56dJHNf6V05r202?t=http%3A%2F%2Fwww.pcouncil.org%2Fwp-content%2Fuploads%2FPFMC_Audio_Diagram_GoToMeeting.pdf&si=6706403137290240&pi=3e8f7565-3109-406a-8f2d-c0dfb39dbb8d*) for best practices). Please use your telephone for the audio portion of the meeting by dialing this TOLL number +1 (562) 247–8321 (not a toll-free number); then enter the Attendee phone audio access code 321–364–024; then enter your audio phone pin (shown after joining the webinar). System Requirements for PC-based attendees: Required: Windows® 7, Vista, or XP; for Mac®-based attendees: Required: Mac OS® X 10.5 or newer; and for mobile attendees: iPhone®, iPad®, Android™ phone or Android tablet (See the GoToMeeting Webinar Apps).

You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2280, extension 425 for technical assistance. A public listening station will also be provided at the Pacific Council office.

Council address: Pacific Council, 7700 NE. Ambassador Place, Suite 101, Portland, Oregon 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Burner, Pacific Council, (503) 820–2414.

SUPPLEMENTARY INFORMATION: The STT, SAS, and MEW will discuss items on the Pacific Council's September 2015 meeting agenda. Major topics include: Salmon Methodology Review, Sacramento River Winter Chinook Update, 2016 Pacific Halibut Catch Sharing Plan and Annual Regulations, and the Unmanaged Forage Fish Regulations. Other topics may include one or more of the Pacific Council's scheduled Administrative Matters. Public comments during the webinar will be received from attendees at the discretion of the STT, SAS, and MEW Chairs.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2280, extension 425 at least 5 days prior to the meeting date.

Dated: August 12, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–20204 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Invention Promoters/Promotion Firms Complaints

ACTION: Proposed collection; comment request

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the extension of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before October 16, 2015.

ADDRESSES: Written comments may be submitted by any of the following methods:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0044 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Cathie Kirik, Mail Stop 24, Commissioner for Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8040; or by email at *Cathie.Kirik@uspto.gov* with ''0651–0044 comment'' in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

Under the Inventors' Rights Act of 1999, as found in 35 U.S.C. 297 and implemented by 37 CFR part 4, the United States Patent and Trademark Office (USPTO) is required to provide a forum for the publication of complaints concerning invention promoters and responses from the invention promoters to these complaints. An individual may submit a complaint concerning an invention promoter to the USPTO, which will forward the complaint to the invention promoter for response. The complaints and responses will be published and made available to the public on the USPTO Web site. The USPTO does not investigate these complaints or participate in any legal proceedings against invention promoters or promotion firms.

Complaints submitted to the USPTO must (1) identify the name and address of the complainant and the invention promoter or promotion firm; (2) explain the basis for the complaint; and (3) include the signature of the complainant. The identifying information is necessary so that the USPTO can both forward the complaint to the invention promoter or promotion firm as well as notify the complainant that the complaint has been forwarded. Complainants should understand that the complaints will be forwarded to the invention promoter for response and that the complaint and response will be made available to the public as required by the Inventors' Rights Act. If the USPTO does not receive a response from the invention promoter, the complaint will still be published without the response. The USPTO does not accept complaints under this program if the complainant requests confidentiality.

This information collection includes one form, Complaint Regarding Invention Promoter (PTO/SB/2048A), which is used by the public to submit a complaint under this program. This form is available for download from the USPTO Web site. Use of this form is not mandatory, and the complainant may submit their complaint without the form via any of the approved methods of collection as long as the complainant includes the necessary information and the submission is clearly marked as a complaint filed under the Inventors' Rights Act. There is no associated form for submitting responses to the complaints.

II. Method of Collection

By mail, facsimile, or hand delivery to the USPTO.

III. Data

OMB Number: 0651–0044.

IC Instruments and Forms: The individual instruments in this collection, as well as their associated forms, are listed in the table below.

Type of Review: Revision of a Previously Existing Information Collection.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 50 responses per year. Of this total, the USPTO expects that 100% will be submitted on paper.

Estimated Time per Response: The USPTO estimates that it will take the public approximately 15 minutes (0.25 hours) to gather the necessary information, prepare the form, and submit a complaint to the USPTO and approximately 30 minutes (0.5 hours) for an invention promoter or promotion firm to prepare and submit a response to a complaint.

Estimated Total Annual Hour Burden: 17.5 hours.

Estimated Total Annual Cost Burden (Hourly): $3,026.25. The USPTO expects that complaints will be prepared by paraprofessionals or independent inventors. Using the average of the paraprofessional rate of $125 per hour and the estimated rate of $30 per hour for independent inventors, the USPTO estimates that the average rate for preparing the complaints will be approximately $77.50 per hour.

The USPTO expects that the responses to the complaints will be prepared by attorneys or invention promoters. Using the average of the professional rate of $389 per hour for attorneys in private firms and the estimated rate of $100 per hour for invention promoters, the USPTO estimates that the average rate for preparing the responses to the complaints will be approximately $244.50 per hour. The time per response, estimated annual responses, and estimated annual hour burden associated with each instrument in this information collection is shown in the table below.

IC No.	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) = (a) × (b)	Rate ($/hr) (d)	Total cost ($/yr) (e) = (c) × (d)
1	Complaint Regarding Invention Promoter (PTO/SB/2048).	0.25	30	7.5	$77.50	$581.25
2	Responses to the Complaints	0.50	20	10	224.50	2,445.00
Totals			50	17.5		3,026.25

Estimated Total Annual Cost Burden (Non-Hourly): $493.70. There are no capital startup, maintenance, or operating fees associated with this collection, nor are there filing or processing fees. There is, however, a non-hourly cost burden associated with this collection in the form of postage costs.

For this collection, it is estimated that 30 complaints will be received by mail. The USPTO estimates that the first-class postage cost for a mailed complaint will be $0.49. Promotion firms may choose to send responses to complaints using overnight mail service at an estimated cost of $23.95 per response. The USPTO estimates that it will receive 20 responses to complaints. Therefore, the total postage cost associated with this collection will be approximately $493.70. As there are no other annual (non-hourly) costs associated with this collection, the USPTO therefore estimates that the total annual (non-hourly) cost burden for this collection, in the form of postage costs, is $493.70 per year.

IV. Request for Comments

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information, including the validity of the methodology and assumptions 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 respondents, including through the use of automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: August 6, 2015.

Marcie Lovett,

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

[FR Doc. 2015–20192 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

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

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

Agency: United States Patent and Trademark Office, Commerce.

Title: Patents for Humanity Program.

OMB Control Number: 0651–0066.

Form Number(s):

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

Type of Request: Regular.

Number of Respondents: 110 responses per year.

Average Minutes per Response: 60 minutes (attorney) or 180 minutes (paralegal) for the Humanitarian Program Application, and 60 minutes for the Petition to Extend the Redemption Period of the Humanitarian Awards Certificate.

Burden Hours: 410.

Cost Burden: $0.

Needs and Uses

The Patents for Humanity Program is designed to incentivize the distribution of patented technologies or products to address humanitarian needs, and is open to any patent owners or patent licensees, including inventors who have not assigned their ownership rights to others, assignees, and exclusive or non-exclusive licensees. Applications are considered in five categories: Medicine, Nutrition, Sanitation, Household Energy, and Living Standards.

The USPTO has developed two application forms that applicants can use to apply for participation in the Patents for Humanity Program—one application covers the humanitarian uses of technologies or products and the other application covers humanitarian research. Applicants may optionally provide contact information for the public to reach them with any inquiries. Additionally, applicants may provide non-public contact information by email to the USPTO in order to be notified about their award status. Applications must be submitted electronically as described at *http://www.uspto.gov/patentsforhumanity.* Complete submitted applications will be available on the public Web site after being screened for inappropriate material.

The applications are reviewed by external judges working independently. A selection committee composed of representatives from other federal agencies and laboratories will make recommendations for the awards based on the judges' reviews. Those applicants who are selected for an award will receive a certificate redeemable to accelerate select matters before the USPTO and public recognition of their efforts, including an awards ceremony at the USPTO. The certificates can be redeemed to accelerate one of the following matters: an *ex parte* reexamination proceeding, including one appeal to the Patent Trial and Appeal Board (PTAB) from that proceeding; a patent application, including one appeal to the PTAB from that application; or an appeal to the PTAB of a claim twice rejected in a patent application or reissue application or finally rejected in an *ex parte* reexamination, without accelerating the underlying matter which generated the appeal. The certificates cannot be transferred to other parties.

Affected Public: Individuals or households, businesses or other for-profits; not-for-profit institutions.

Frequency: Annually.

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

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

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

Further information can be obtained by:

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

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

Written comments and recommendations for the proposed information collection should be sent on or before September 16, 2015 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Dated: August 6, 2015.

Marcie Lovett,

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

[FR Doc. 2015–20193 Filed 8–14–15; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2015–OS–0081]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: Notice to delete a System of Records.

SUMMARY: The Office of the Secretary of Defense is deleting a system of records notice from its existing inventory of record systems subject to the Privacy Act of 1974, as amended. The system of records notice is DA&M 02, Director of Administration and Management (DA&M) Mentoring Program (March 8, 2013, 78 FR 15006).

DATES: Comments will be accepted on or before September 16, 2015. This proposed action will be effective on the day following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mrs. Cindy Allard at (571) 372–0461.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Defense Privacy and Civil Liberties Division Web site at *http://dpcld.defense.gov/.* The Office of the Secretary of Defense proposes to delete one system of records notice from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: August 11, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

Deletion:

DA&M 02

Director of Administration and Management (DA&M) Mentoring Program (March 8, 2013, 78 FR 15006)

REASON:

The mentoring program is no longer an active program and the records have been destroyed, therefore, this notice can be deleted.

[FR Doc. 2015–20150 Filed 8–14–15; 8:45 am]

BILLING CODE 5001–06–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: EG15–112–000.
Applicants: Silver State Solar Power South, LLC.
Description: Notice of Self-certification of Exempt Wholesale Generator Status of Silver State Solar Power South, LLC.
Filed Date: 8/11/15.
Accession Number: 20150811–5097.
Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: EG15–113–000.
Applicants: Recurrent Energy, LLC.
Description: Notice of Self-Certification of EG of RE Garland, LLC.
Filed Date: 8/11/15.
Accession Number: 20150811–5121.
Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: EG15–114–000.
Applicants: Recurrent Energy, LLC.
Description: Self-Certification of EG of RE Garland A, LLC.
Filed Date: 8/11/15.
Accession Number: 20150811–5126.
Comments Due: 5 p.m. ET 9/1/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2964–008.
Applicants: Selkirk Cogen Partners, L.P.
Description: Supplement to July 1, 2015 Notice of Non-Material Change in Status of Selkirk Cogen Partners, L.P.
Filed Date: 8/11/15.
Accession Number: 20150811–5077.
Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: ER15–2135–000.
Applicants: Alexander Wind Farm, LLC.
Description: Supplement to July 9, 2015 Alexander Wind Farm, LLC tariff filing.
Filed Date: 8/6/15.
Accession Number: 20150806–5086.
Comments Due: 5 p.m. ET 8/27/15.

Docket Numbers: ER15–2348–000.
Applicants: Tucson Electric Power Company.
Description: Report Filing: Supplement to Filing of Amendments to Rate Schedule No. 102 to be effective N/A.
Filed Date: 8/7/15.
Accession Number: 20150807–5125.
Comments Due: 5 p.m. ET 8/28/15.

Docket Numbers: ER15–2409–000.
Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2015–08–11_SA 2825 MidAmerican Energy-Highland Wind Energy II GIA (J285) to be effective 8/4/2015.

Filed Date: 8/11/15.

Accession Number: 20150811–5037.

Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: ER15–2410–000.

Applicants: Public Service Company of New Mexico.

Description: Initial rate filing: Executed Expedited Service Agreement between PNM and Arabella Wind, LLC to be effective 7/16/2015.

Filed Date: 8/11/15.

Accession Number: 20150811–5100.

Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: ER15–2411–000.

Applicants: PacifiCorp.

Description: Tariff Cancellation: Termination of NW Energy AMPS 230 kV Line 46 MW Construct Agmt to be effective 10/29/2015.

Filed Date: 8/11/15.

Accession Number: 20150811–5124.

Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: ER15–2412–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1884R4 Westar Energy, Inc. NITSA and NOA to be effective 8/1/2015.

Filed Date: 8/11/15.

Accession Number: 20150811–5135.

Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: ER15–2413–000.

Applicants: ITC Midwest LLC.

Description: § 205(d) Rate Filing: Filing of CIAC Agreement with Clarke Electric to be effective 10/12/2015.

Filed Date: 8/11/15.

Accession Number: 20150811–5142.

Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: ER15–2414–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1885R4 Westar Energy, Inc. (Bronson) NITSA and NOA to be effective 8/1/2015.

Filed Date: 8/11/15.

Accession Number: 20150811–5143.

Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: ER15–2415–000.

Applicants: ISO New England Inc.

Description: Compliance filing: Errata to Revision Related to Order No. 676–H to be effective 5/15/2015.

Filed Date: 8/11/15.

Accession Number: 20150811–5144.

Comments Due: 5 p.m. ET 9/1/15.

Docket Numbers: ER15–2416–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1887R4 Westar Energy, Inc. (Elsmore) NITSA and NOA to be effective 8/1/2015.

Filed Date: 8/11/15.

Accession Number: 20150811–5172.

Comments Due: 5 p.m. ET 9/1/15.

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: August 11, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–20195 Filed 8–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF15–22–000]

Equitrans, L.P.; Notice of Intent To Prepare an Environmental Impact Statement for the Planned Equitrans Expansion Project, and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will discuss the potential environmental effects of the Equitrans Expansion Project (EEP, or Project) involving construction and operation of facilities by Equitrans, L.P. (Equitrans) in Allegheny, Washington, and Green Counties, Pennsylvania and Wetzel County, West Virginia, in the Commission's environmental impact statement (EIS) currently under preparation for the planned Mountain Valley Pipeline (MVP) Project (FERC Docket No. PF15–3–000). The Project is designed to transport natural gas from the northern portion of Equitrans' system south to a future interconnection with MVP, as well as existing interconnects on the southern portion of Equitrans' system with Texas Eastern Transmission, LP and Dominion Transmission, Inc. Because of the interconnection with MVP, the Commission staff will evaluate the two projects jointly in the EIS. This EIS will be used by the Commission in its decision-making process to determine whether the MVP and EEP Projects are in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the EEP. You can make a difference by providing us with your specific comments or concerns about the Project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EIS. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before September 14, 2015.

If you sent comments on the EEP to the Commission before the opening of this docket on April 9, 2015, you will need to re-file those comments in Docket No. PF15–22–000 to ensure they are considered as part of this proceeding. This scoping period is established to receive comments on the EEP, and comments previously filed with the FERC regarding the MVP Project should not be refiled under the EEP docket.

This notice is being sent to the Commission's current environmental mailing list for this Project. State and local government representatives should notify their constituents of this planned Project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a representative of Equitrans may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the Project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site (*www.ferc.gov*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to

participate in the Commission's proceedings.

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.''* If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (PF15–22–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Summary of the Planned Project

According to Equitrans, the EEP is designed to allow shippers the flexibility of transporting up to 600,000 dekatherms per day of natural gas produced in the Appalachian Basin to potential markets in the Northeast, Mid-Atlantic, and Southeastern United States. The EEP would consist of the following facilities:

- A new 3.0-mile-long, 30-inch-diameter pipeline and a new 4.2-mile-long, 20-inch-diameter pipeline in Allegheny and Washington Counties Pennsylvania (H–316 Pipeline and H–318 Pipeline);
- a new Redhook Compressor Station, to replace the existing Pratt Compressor Station in Green County, Pennsylvania;
- an interconnect with the planned MVP Project and a tap on Equitrans' existing H–302 pipeline in Wetzel County, West Virginia (Webster Interconnection and Mobley Tap);
- a new extension of an existing 6-inch-diameter pipeline and an existing 12-inch-diameter pipeline extending for 0.2-mile in Green County, Pennsylvania (M–80 Pipeline and H–158 Pipeline);
- a new approximately 200-foot-long, 16-inch-diameter pipeline in Wetzel County, West Virginia (H–319 Pipeline);
- a new approximately 55-foot-long extension of an existing 12-inch pipeline in Green County, Pennsylvania (H–305 Pipeline);
- pig launchers and receivers; [1] and
- four meter and regulation stations.

The general location of the Project facilities is shown in appendix 1.

Land Requirements for Construction

Construction of the planned facilities would disturb approximately 207 acres of land for the aboveground facilities and the pipelines. Following construction, Equitrans would maintain approximately 64 acres for permanent operation of the Project's facilities; the remaining acreage would be restored and revert to former uses. The actual acreage affected will be determined more precisely as Project design proceeds and likely will increase above these preliminary estimates.

The EIS Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. The NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EIS on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EIS. We will consider all filed comments during the preparation of the EIS.

In the EIS we will discuss impacts that could occur as a result of the construction and operation of the planned project under these general headings:

- Geology and soils;
- water resources and wetlands;
- cultural resources;
- vegetation and wildlife;
- cultural resources;
- land use, recreation, and visual resources;
- air quality and noise;
- public safety; and
- cumulative impacts.

The EIS will present our independent analysis of the issues. We will evaluate possible alternatives to the planned Project or portions of the Project. For specific resources, we would make recommendations on how to avoid, minimize, or mitigate impacts, in addition to the measures proposed by Equitrans.

Although no formal application has been filed, we have already initiated our environmental review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives an application. As part of our pre-filing review, we have begun to contact some federal and state agencies to discuss their involvement in the scoping process and the preparation of the EIS.

We will publish and distribute the draft EIS for public comment. After the comment period, we will consider all timely comments and revise the document, as necessary, before issuing a final EIS. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section of this notice.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this project to formally cooperate with us in the preparation of the EIS.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice. The U.S. Department of Agriculture Forest Service, U.S. Army Corps of Engineers, U.S. Environmental Protection Agency, U.S. Department of Transportation, West Virginia Department of Natural Resources, and the West Virginia Department of Environment Protection have already agreed to be cooperating agencies in the development of the EIS for the MVP Project.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the

[1] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

[2] The pronouns ''we'', ''us'', and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, part 1501.6.

applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the Project's potential effects on historic properties.[4] We will define the Project-specific Area of Potential Effects (APE) in consultation with the SHPO(s) as the Project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EIS for this Project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the planned facilities and the environmental information provided by Equitrans. This preliminary list of issues may change based on your comments and our analysis:

- Steep slopes;
- erosion control;
- alternatives and their potential impacts on a range of resources; and
- cumulative impacts.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Indian Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for Project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned Project.

Copies of the completed draft EIS will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the compact disc version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

Once Equitrans files its application with the Commission, you may want to become an ''intervenor,'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.* Instructions for becoming an intervenor are in the ''Document-less Intervention Guide'' under the ''e-filing'' link on the Commission's Web site. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* PF15–22). Be sure you have selected an appropriate date range. 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. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public meetings or site visits, if scheduled, will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: August 11, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–20199 Filed 8–14–15; 8:45 am]

BILLING CODE 6717–01–P

[4] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER15–2304–000]

Oildale Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Oildale 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 August 31, 2015.

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 Web site 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: August 11, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–20196 Filed 8–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–539–000]

Columbia Gulf Transmission, LLC; Notice of Application

Take notice that on July 29, 2015, Columbia Gulf Transmission, LLC (Columbia Gulf), 5151 San Felipe, Suite 2500, Houston, Texas 77056, filed an application under section 7(c) of the Natural Gas Act and Part 157 of the Commission's regulations requesting authorization to construct, own and operate 51,800 horsepower at two greenfield compressor stations in Carter, Menifee and Montgomery Counties, Kentucky, to enable up to 621,000 Dekatherms per day (Rayne XPress Project) of firm transportation on its system, all as more fully described in the application.

The filing may also be viewed on the web 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 at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, (202) 502–8659.

Any questions regarding the proposed project should be directed to William A. Sala, Jr., Senior Counsel, Columbia Gulf Transmission, LLC, 5151 San Felipe, Suite 2500, Houston, Texas 77056; telephone: 713–386–3743.

On June 22, 2015 in Docket No. CP15–514–000, the Commission issued a Notice of Application (June 22 Notice) for Columbia Gulf's affiliate, Columbia Gas Transmission, LLC's (Columbia Gas) Leach XPress Project. The June 22 Notice stated that the Rayne Express Project may have some connection to Columbia Gas' Leach Xpress Project, and further, that ''Until the details of the Rayne Xpress project are filed and more fully understood, the Commission cannot begin preparation of the Environmental Impact Statement (EIS) to comply with the NEPA of 1969.'' Columbia Gulf's Rayne XPress application filing confirms the connection between the Leach XPress and Rayne XPress Projects and thus, we can begin our analysis.

Within 90 days after the date of this Notice of Application for the Rayne Xpress project, the Commission staff will issue a Notice of Schedule for Environmental Review that will indicate the anticipated date for the Commission's staff issuance of the final EIS analyzing both the Leach XPress and Rayne XPress proposals. The issuance of a Notice of Schedule for Environmental Review will also serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's final EIS.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: September 1, 2015.

Dated: August 11, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–20200 Filed 8–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR15–34–000]

Saddle Butte Rockies Midstream, LLC; Notice of Request for Waiver

Take notice that on August 7, 2015, pursuant to Rule 204 of the Commission's Rules of Practices and Procedure, 18 CFR 385.204 (2014), Saddle Butte Rockies Midstream, LLC filed a petition requesting temporary waiver of the tariff filing and reporting requirements of sections 6 and 20 of the Interstate Commerce Act and parts 341 and 357 of the Commission's regulations, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in

accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site 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.

Comment Date: 5 p.m. Eastern time on August 21, 2015.

Dated: August 11, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–20197 Filed 8–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER15–2243–000]

Silver State Solar Power South, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Silver State Solar Power South, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 31, 2015.

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 Web site 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: August 11, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–20201 Filed 8–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF15–17–000]

Texas Eastern Transmission, LP; Notice of Intent To Prepare an Environmental Assessment for the Planned Access South, Adair Southwest, and Lebanon Extension Projects and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Access South, Adair Southwest, and Lebanon Extension Projects (Projects) in Docket No. PF15–17–000. The projects involve construction, abandonment, and operation of facilities by Texas Eastern Transmission, LP (Texas Eastern) that would provide incremental pipeline transportation service from the Appalachia area natural gas supply basins to markets in the Midwest and Southeast. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the Projects. You can make a difference by providing us with your specific comments or concerns about the Projects. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before September 10, 2015.

If you sent comments on the Projects to the Commission before the opening of this docket on March 13, 2015, you will need to file those comments in Docket No. PF15–17–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this planned Projects and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to

construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the Projects, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site (*www.ferc.gov*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.''* If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (PF15–17–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Summary of the Planned Project

The planned pipeline facilities for the Projects include 19.9 miles of 36-inch diameter pipeline loop [1] in three segments, most of which would be either within or adjacent to Texas Eastern's existing rights-of-way in Meigs, Athens, Noble, Monroe Counties, Ohio. Proposed modifications to aboveground facilities would include the installation of new compression and additional modifications necessary to allow for bidirectional flow, increased horsepower requirements, and meter reversals at thirteen existing compressor stations which are expected to be located primarily within Texas Eastern's current footprint.

At the Five Points Compressor Station in Pickaway County, Ohio, Texas Eastern would install a new 10,000 horsepower (hp) electric compressor and would abandon in-place three 2,000 hp electric compressor units. A new 16,875 hp electric compressor would be added at the Tompkinsville Compressor Station in Monroe County, Kentucky.

Planned modifications at thirteen existing compressor station sites would include piping modifications to accommodate bi-directional flow capability along Texas Eastern's existing mainline. These modifications are proposed at the following compressor stations:

- Holbrook Compressor Station in Greene County, Pennsylvania;
- Lebanon Compressor Station in Warren County, Ohio;
- Five Points Compressor Station in Pickaway County, Ohio;
- Somerset Compressor Station in Perry County, Ohio;
- Berne Compressor Station in Monroe County, Ohio;
- Athens Compressor Station in Athens County, Ohio;
- Owingsville Compressor Station in Bath County, Kentucky;
- Danville Compressor Station in Lincoln County, Kentucky;
- Tompkinsville Compressor Station in Monroe County, Kentucky;
- Gladeville Compressor Station in Wilson County, Tennessee;
- Barton Compressor Station in Colbert County, Alabama;
- Egypt Compressor Station in Monroe County, Mississippi; and
- Kosciusko Compressor Station in Attala County, Mississippi.

In addition two pig [2] launcher/receivers would be relocated and two new pig launcher/receivers would be installed in Monroe County, Ohio.

The general location of the Projects facilities is shown in appendix 1.[3]

Land Requirements for Construction

Construction of the planned facilities would disturb about 631.9 acres of land for the aboveground facilities and the pipeline, including access roads. Following construction, Texas Eastern would maintain about 70.7 acres for permanent operation of the Projects' facilities; the remaining acreage would be restored and revert to former uses. The planned loops would be mostly adjacent to Texas Eastern's existing pipeline rights-of-way and construction at the compressor stations would occur at existing facilities where no permanent expansion of the facilities would occur.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [4] to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the planned Projects under these general headings:

- Geology and soils;
- land use;
- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species;
- public safety; and
- cumulative impacts.

We will also evaluate possible alternatives to the planned Projects or portions of the Projects, and make

[1] A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

[2] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

[3] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[4] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, we have already initiated our NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives an application. As part of our pre-filing review, we have begun to contact some federal and state agencies to discuss their involvement in the scoping process and the preparation of the EA.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before we make our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this project to formally cooperate with us in the preparation of the EA.[5] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the Projects' potential effects on historic properties.[6] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO(s) as the Projects develop. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for the Projects will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Projects. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned Projects.

If we publish and distribute the EA, copies of the EA will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

Once Texas Eastern files its application with the Commission, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.* Instructions for becoming an intervenor are in the ''Document-less Intervention Guide'' under the ''e-filing'' link on the Commission's Web site. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* PF15–17). Be sure you have selected an appropriate date range. 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. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: August 11, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–20198 Filed 8–14–15; 8:45 am]

BILLING CODE 6717–01–P

[5] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[6] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9932–28–OSWER]

Twenty-Eighth Update of the Federal Agency Hazardous Waste Compliance Docket

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Since 1988, the Environmental Protection Agency (EPA) has maintained a Federal Agency Hazardous Waste Compliance Docket (''Docket'') under Section 120(c) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Section 120(c) requires EPA to establish a Docket that contains

certain information reported to EPA by Federal facilities that manage hazardous waste or from which a reportable quantity of hazardous substances has been released. As explained further below, the Docket is used to identify Federal facilities that should be evaluated to determine if they pose a threat to public health or welfare and the environment and to provide a mechanism to make this information available to the public.

This notice identifies the Federal facilities not previously listed on the Docket and reported to EPA since the last update of the Docket on December 31, 2014. In addition to the list of additions to the Docket, this notice includes a section with revisions of the previous Docket list. Thus, the revisions in this update include 21 additions and 90 deletions to the Docket since the previous update. At the time of publication of this notice, the new total number of Federal facilities listed on the Docket is 2,323.

DATES: This list is current as of July 13, 2015.

FOR FURTHER INFORMATION CONTACT: Electronic versions of the Docket and more information on its implementation can be obtained at *http://www2.epa.gov/fedfac/previous-federal-agency-hazardous-waste-compliance-docket-updates* by clicking on the link for *Update #28 to the Federal Agency Hazardous Waste Compliance Docket* or by contacting Benjamin Simes (*Simes.Benjamin@epa.gov*), Federal Agency Hazardous Waste Compliance Docket Coordinator, Federal Facilities Restoration and Reuse Office (Mail Code 5106P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Table of Contents

1.0 Introduction

Section 120(c) of CERCLA, 42 United States Code (U.S.C.) 9620(c), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), requires EPA to establish the Federal Agency Hazardous Waste Compliance Docket. The Docket contains information on Federal facilities that manage hazardous waste and such information is submitted by Federal agencies to EPA under Sections 3005, 3010, and 3016 of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6925, 6930, and 6937. Additionally, the Docket contains information on Federal facilities with a reportable quantity of hazardous substances that has been released and such information is submitted by Federal agencies to EPA under Section 103 of CERCLA, 42 U.S.C. 9603. Specifically, RCRA Section 3005 establishes a permitting system for certain hazardous waste treatment, storage, and disposal (TSD) facilities; RCRA Section 3010 requires waste generators, transporters and TSD facilities to notify EPA of their hazardous waste activities; and RCRA Section 3016 requires Federal agencies to submit biennially to EPA an inventory of their Federal hazardous waste facilities. CERCLA Section 103(a) requires the owner or operator of a vessel or onshore or offshore facility to notify the National Response Center (NRC) of any spill or other release of a hazardous substance that equals or exceeds a reportable quantity (RQ), as defined by CERCLA Section 101. Additionally, CERCLA Section 103(c) requires facilities that have ''stored, treated, or disposed of'' hazardous wastes and where there is ''known, suspected, or likely releases'' of hazardous substances to report their activities to EPA.

CERCLA Section 120(d) requires EPA to take steps to assure that a Preliminary Assessment (PA) be completed for those sites identified in the Docket and that the evaluation and listing of sites with a PA be completed within a reasonable time frame. The PA is designed to provide information for EPA to consider when evaluating the site for potential response action or inclusion on the National Priorities List (NPL).

The Docket serves three major purposes: (1) To identify all Federal facilities that must be evaluated to determine whether they pose a threat to human health and the environment sufficient to warrant inclusion on the National Priorities List (NPL); (2) to compile and maintain the information submitted to EPA on such facilities under the provisions listed in Section 120(c) of CERCLA; and (3) to provide a mechanism to make the information available to the public.

The initial list of Federal facilities to be included on the Docket was published in the **Federal Register** on February 12, 1988 (53 FR 4280). Since then, updates to the Docket have been published on November 16, 1988 (53 FR 46364); December 15, 1989 (54 FR 51472); August 22, 1990 (55 FR 34492); September 27, 1991 (56 FR 49328); December 12, 1991 (56 FR 64898); July 17, 1992 (57 FR 31758); February 5, 1993 (58 FR 7298); November 10, 1993 (58 FR 59790); April 11, 1995 (60 FR 18474); June 27, 1997 (62 FR 34779); November 23, 1998 (63 FR 64806); June 12, 2000 (65 FR 36994); December 29, 2000 (65 FR 83222); October 2, 2001 (66 FR 50185); July 1, 2002 (67 FR 44200); January 2, 2003 (68 FR 107); July 11, 2003 (68 FR 41353); December 15, 2003 (68 FR 69685); July 19, 2004 (69 FR 42989); December 20, 2004 (69 FR 75951); October 25, 2005 (70 FR 61616); August 17, 2007 (72 FR 46218); November 25, 2008 (73 FR 71644); October 13, 2010 (75 FR 62810); November 6, 2012 (77 FR 66609), March 18, 2013 (78 FR 16668), January 6, 2014 (79 FR 654), and December 31, 2014 (79 FR 78850). This notice constitutes the twenty-eighth update of the Docket.

This notice provides some background information on the Docket. Additional information on the Docket requirements and implementation are found in the Docket Reference Manual, Federal Agency Hazardous Waste Compliance Docket found at *http://www2.epa.gov/fedfac/docket-reference-manual-federal-agency-hazardous-waste-compliance-docket-interim-final* or obtained by calling the Regional Docket Coordinators listed below. This notice also provides changes to the list of sites included on the Docket in three areas: (1) Additions, (2) Deletions, and (3) Corrections. Specifically, additions are newly identified Federal facilities that have been reported to EPA since the last update and now are included on the Docket; the deletions section lists Federal facilities that EPA is deleting from the Docket.[1] The information submitted to EPA on each Federal facility is maintained in the Docket repository located in the EPA Regional office of the Region in which the Federal facility is located; for a description of the information required under those provisions, *see* 53 FR 4280 (February 12, 1988). Each repository contains the documents submitted to EPA under the reporting provisions and correspondence relevant to the reporting provisions for each Federal facility.

In prior updates, information was also provided regarding No Further Remedial Action Planned (NFRAP) status changes. However, information on NFRAP and NPL status is no longer being provided separately in the Docket update as it is now available at: *http://www2.epa.gov/fedfac/previous-federal-*

[1] See Section 3.2 for the criteria for being deleted from the Docket.

agency-hazardous-waste-compliance-docket-updates or by contacting the EPA HQ Docket Coordinator at the address provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

2.0 Regional Docket Coordinators

Contact the following Docket Coordinators for information on Regional Docket repositories:

Martha Bosworth (HBS), US EPA Region 1, 5 Post Office Square, Suite 100, Mail Code: OSRR07–2, Boston MA 02109–3912, (617) 918–1407.

Helen Shannon (ERRD), US EPA Region 2, 290 Broadway, New York, NY 10007–1866, (212) 637– 4260.

Joseph Vitello (3HS12), US EPA Region 3, 1650 Arch Street, Philadelphia, PA 19107, (215) 814–3354.

Dawn Taylor (4SF–SRSEB), US EPA Region 4, 61 Forsyth St., SW., Atlanta, GA 30303, (404) 562–8575.

Michael Chrystof (SR–6J), US EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 353–3705.

Philip Ofosu (6SF–RA), US EPA Region 6, 1445 Ross Avenue, Dallas, TX 75202–2733, (214) 665–3178.

Paul Roemerman (SUPRERSP), US EPA Region 7, 11201 Renner Blvd., Lenexa, KS 66219, (913) 551–7694.

Ryan Dunham (EPR–F), US EPA Region 8, 1595 Wynkoop Street, Denver, CO 80202, (303) 312–6627.

Leslie Ramirez (SFD–6–1), US EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3978.

Monica Lindeman (ECL, ABU), US EPA Region 10, 1200 Sixth Avenue, Suite 900, ECL–112, Seattle, WA 98101, (206) 553–5113.

3.0 Revisions of the Previous Docket

This section includes a discussion of the additions and deletions to the list of Docket facilities since the previous Docket update.

3.1 Additions

In this notice, 21 Federal facilities are being added to the Docket, primarily because of new information obtained by EPA (for example, recent reporting of a facility pursuant to RCRA Sections 3005, 3010, or 3016 or CERCLA Section 103). CERCLA Section 120, as amended by the Defense Authorization Act of 1997, specifies that EPA take steps to assure that a Preliminary Assessment (PA) be completed within a reasonable time frame for those Federal facilities that are included on the Docket. Among other things, the PA is designed to provide information for EPA to consider when evaluating the site for potential response action or listing on the NPL.

3.2 Deletions

In this notice, 90 Federal facilities are being deleted from the Docket. There are no statutory or regulatory provisions that address deletion of a facility from the Docket. However, if a facility is incorrectly included on the Docket, it may be deleted from the Docket. The criteria EPA uses in deleting sites from the Docket include: A facility for which there was an incorrect report submitted for hazardous waste activity under RCRA (*e.g.,* 40 CFR 262.44); a facility that was not Federally-owned or operated at the time of the listing; a facility included more than once (*i.e.,* redundant listings); or when multiple facilities are combined under one listing. (See Docket Codes (*Categories for Deletion of Facilities*) for a more refined list of the criteria EPA uses for deleting sites from the Docket. Facilities being deleted no longer will be subject to the requirements of CERCLA Section 120(d).

3.3 Corrections

Changes necessary to correct the previous Docket are identified by both EPA and Federal agencies. The corrections section may include changes in addresses or spelling, and corrections of the recorded name and ownership of a Federal facility. In addition, changes in the names of Federal facilities may be made to establish consistency in the Docket or between the Superfund Enterprise Management System (SEMS) and the Docket. For the Federal facility for which a correction is entered, the original entry is as it appeared in previous Docket updates. The corrected update is shown directly below, for easy comparison. This notice includes 68 corrections.

4.0 Process for Compiling the Updated Docket

In compiling the newly reported Federal facilities for the update being published in this notice, EPA extracted the names, addresses, and identification numbers of facilities from four EPA databases—the Emergency Response Notification System (ERNS), the Biennial Inventory of Federal Agency Hazardous Waste Activities, the Resource Conservation and Recovery Act Information System (RCRAInfo), and CERCLIS—that contain information about Federal facilities submitted under the four provisions listed in CERCLA Section 120(c).

EPA assures the quality of the information on the Docket by conducting extensive evaluation of the current Docket list with the information obtained from the databases identified above to determine which Federal facilities were, in fact, newly reported and qualified for inclusion on the update. EPA is also striving to correct errors for Federal facilities that were previously reported. For example, state-owned or privately-owned facilities that are not operated by the Federal government may have been included. Such problems are sometimes caused by procedures historically used to report and track Federal facilities data. Representatives of Federal agencies are asked to write to the EPA HQ Docket Coordinator at the address provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice if revisions of this update information are necessary.

5.0 Facilities Not Included

Certain categories of facilities may not be included on the Docket, such as: (1) Federal facilities formerly owned by a Federal agency that at the time of consideration was not Federally-owned or operated; (2) Federal facilities that are small quantity generators (SQGs) that have never generated more than 1,000 kg of hazardous waste in any month; (3) Federal facilities that are solely hazardous waste transportation facilities, as reported under RCRA Section 3010; and (4) Federal facilities that have mixed mine or mill site ownership.

An EPA policy issued in June 2003 provided guidance for a site-by-site evaluation as to whether ''mixed ownership'' mine or mill sites, typically created as a result of activities conducted pursuant to the General Mining Law of 1872 and never reported under Section 103(a), should be included on the Docket. For purposes of that policy, mixed ownership mine or mill sites are those located partially on private land and partially on public land. This policy is found at *http://www2.epa.gov/fedfac/policy-listing-mixed-ownership-mine-or-mill-sites-created-result-general-mining-law-1872*. The policy for not including these facilities may change; facilities now not included may be added at some point if EPA determines that they should be included.

6.0 Facility NPL Status Reporting, Including NFRAP Status

EPA typically tracks the NPL status of Federal facilities listed on the Docket. An updated list of the NPL status of all Docket facilities, as well as their NFRAP status, is available at *http://www2.epa.gov/fedfac/previous-federal-agency-hazardous-waste-compliance-docket-updates* or by contacting the EPA HQ Docket Coordinator at the address provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. In prior updates, information regarding NFRAP status changes was provided separately.

7.0 Information Contained on Docket Listing

The updated information is provided in three tables. The first table is a list of new Federal facilities that are being added to the Docket, the second table is a list of Federal facilities that are being deleted from the Docket, and the third table is for corrections.

The Federal facilities listed in each table are organized by the date reported. Under each heading is listed the name and address of the facility, the Federal agency responsible for the facility, the statutory provision(s) under which the facility was reported to EPA, and a code.[2] The code key precedes the lists.

The statutory provisions under which a Federal facility is reported are listed in a column titled ''Reporting Mechanism.'' Applicable mechanisms are listed for each Federal facility: for example, Sections 3005, 3010, 3016, 103(c), or Other. ''Other'' has been added as a reporting mechanism to indicate those Federal facilities that otherwise have been identified to have releases or threat of releases of hazardous substances. The National Contingency Plan 40 CFR 300.405 addresses discovery or notification, outlines what constitutes discovery of a hazardous substance release, and states that a release may be discovered in several ways, including: (1) A report submitted in accordance with Section 103(a) of CERCLA, *i.e.,* reportable quantities codified at 40 CFR part 302; (2) a report submitted to EPA in accordance with Section 103(c) of CERCLA; (3) investigation by government authorities conducted in accordance with Section 104(e) of CERCLA or other statutory authority; (4) notification of a release by a Federal or state permit holder when required by its permit; (5) inventory or survey efforts or random or incidental observation reported by government agencies or the public; (6) submission of a citizen petition to EPA or the appropriate Federal facility requesting a preliminary assessment, in accordance with Section 105(d) of CERCLA; (7) a report submitted in accordance with Section 311(b)(5) of the Clean Water Act; and (8) other sources. As a policy matter, EPA generally believes it is appropriate for Federal facilities identified through the CERCLA discovery and notification process to be included on the Docket.

The complete list of Federal facilities that now make up the Docket and the NPL and NFRAP status are available to interested parties and can be obtained at *http://www2.epa.gov/fedfac/previous-federal-agency-hazardous-waste-compliance-docket-updates* by clicking on the link for *Federal Agency Hazardous Waste Compliance Docket Update #28* or by contacting the EPA HQ Docket Coordinator at the address provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. As of the date of this notice, the total number of Federal facilities that appear on the Docket is 2,323.

Dated: August 3, 2015.

Charlotte Bertrand,

Acting Director, Federal Facilities Restoration and Reuse Office, Office of Solid Waste and Emergency Response.

Categories for Deletion of Facilities

(1) Small-Quantity Generator.Show citation box.

(2) Never Federally Owned and/or Operated.

(3) Formerly Federally Owned and/or Operated but not at time of listing.

(4) No Hazardous Waste Generated.

(5) (This code is no longer used.)

(6) Redundant Listing/Site on Facility.

(7) Combining Sites Into One Facility/Entries Combined.

(8) Does Not Fit Facility Definition.

Categories for Addition of Facilities

(15) Small-Quantity Generator with either a RCRA 3016 or CERCLA 103 Reporting Mechanism.

(16) One Entry Being Split Into Two (or more)/Federal Agency Responsibility Being Split.

(17) New Information Obtained Showing That Facility Should Be Included.

(18) Facility Was a Site on a Facility That Was Disbanded; Now a Separate Facility.

(19) Sites Were Combined Into One Facility.

(19A) New Currently Federally Owned and/or Operated Facility Site.

Categories for Corrections of Information About Facilities

(20) Reporting Provisions Change.

(20A) Typo Correction/Name Change/Address Change.

(21) Changing Responsible Federal Agency. (If applicable, new responsible Federal agency submits proof of previously performed PA, which is subject to approval by EPA.)

(22) Changing Responsible Federal Agency and Facility Name. (If applicable, new responsible Federal Agency submits proof of previously performed PA, which is subject to approval by EPA.)

(24) Reporting Mechanism Determined To Be Not Applicable After Review of Regional Files.

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—ADDITIONS

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
FEDERAL LAW ENFORCMENT TRAINING CENTER.	CHAPEL CROSSING RD	GLYNCO	GA	31524	Department of Homeland Security.	RCRA 3010	19A
USCG Gull Rock Light Station.	2.5 Miles E of Keweenaw Point on Keweenaw Peninsula.	COPPER HARBOR	MI	49918	Department of Homeland Security.	OTHER	19A
USCG Manitou Island Light Station.	5.1 Miles E of Keweenaw Point on Keweenaw Peninsula.	COPPER HARBOR	MI	49918	Department of Homeland Security.	OTHER	19A
BLM QUESTAR PIPELINE COMPANY EAKIN STATION.	HIGHWAY 189 N	KEMMERER	WY	83101	Department of Interior.	RCRA 3010	19A

[2] Each Federal facility listed in the update has been assigned a code that indicates a specific reason for the addition or deletion. The code precedes this list.

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—ADDITIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
DEPARTMENT OF VETERANS AFFAIRS KERRVILLE.	3600 MEMORIAL	KERRVILLE	TX	78028	Department of Veteran Affairs.	RCRA 3010	19A
JAMES J PETERS VA MEDICAL CENTER.	130 WEST KINGSBRIDGE ROAD ROOM GC–100.	BRONX	NY	10468	Department of Veteran Affairs.	RCRA 3010	19A
DEPT OF VETERANS AFFAIRS NY HARBOR HEALTHCARE SYSTEM MANHATTAN CAMPUS.	423 E 23RD ST	NEW YORK	NY	10010	Department of Veteran Affairs.	RCRA 3010	19A
FEDERAL BUREAU OF INVESTIGATION.	935 PENNSYLVANIA AVENUE, NW.	WASHINGTON	DC	20535	Department of Justice.	RCRA 3010	19A
GAINESVILLE JOB CORPS CENTER.	N.E. 40TH TERRACE	GAINESVILLE	FL	32609	Department of Labor.	RCRA 3010	19A
US DOT ST LAWRENCE SEAWAY DEVELOPMENT CORP EISENHOWER LOCK.	76 Barnhart Island Road	Massena (NY)	NY	13662	Department of Transportation.	RCRA 3010	19A
U.S. EPA, REGION 3, ENVIRONMENTAL SCIENCE CENTER.	MAPES ROAD	FORT MEADE	MD	20755	EPA	RCRA 3010	19A
FEDERICO DEGETAU FEDERAL OFFICE BUILDING—INDOOR FIRING RANGE.	150 Carlos Chardon Ave Room 359 (539).	San Juan	PR	00918	General Services Administration.	RCRA 3010	19A
CENTERS FOR DISEASE CONTROL AND PREVENTION.	CLIFTON RD MS–F05	ATLANTA	GA	30333	Health and Human Services.	RCRA 3010	19A
NASA-Johnson Space Center, BUILDING 319.	2101 NASA Parkway	Houston	TX	77058	NASA	CERCLA 103	19A
SMITHSONIAN INSTITUTION.	2 East 91st St	New York	NY	10128	Smithsonian Board of Regents.	RCRA 3010	19A
JOINT BASE LANGLEY–EUSTIS.	SWEENEY BLVD	HAMPTON	VA	23665–2769	U.S. AIR FORCE ..	RCRA 3010	19A
AIR FORCE MEDICAL OPERATIONS AGENCY AFMOA.	601 DAVY CROCKETT RD	SAN ANTONIO	TX	78226–1885	U.S. AIR FORCE ..	RCRA 3010	19A
US ARMY RESERVE CENTER.	18960 S HALSTED ST	HOMEWOOD	IL	60430	U.S. ARMY	RCRA 3010	19A
US ARMY CORPS OF ENGINEERS WHITNEY POINT LAKE AND DAM.	5327 Upper Lisle Road—Rt. 26N.	Whitney Point	NY	13862	U.S. ARMY	RCRA 3010	19A
U.S.ARMY, FORT POLK.	WARRIOR TRAIL, BLDG 350.	FORT POLK	LA	71459	U.S. ARMY	RCRA 3010	19A
US ARMY, WARRENTON TRAINING CENTER, STATION C.	PO BOX 700	WARRENTON	VA	20186	Department of Homeland Security.	RCRA 3010, 103(c).	19A

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—DELETIONS

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Harry S. Truman Animal Import Center.	Fleming Key	Key West	FL	33041	Dept of Agriculture	103c	1
Coastal Plains Experiment Station.	P.O. Box 748	Tifton	GA	31793	Dept of Agriculture	3016	1
FS-National Tree Seed Lab.	Riggins Mill Rd	Dry Branch	GA	31020	Dept of Agriculture	3010	1
Nantahala Nf: Graham County Landfill.	North of Snowbird Mountain	Robbinsville	NC		Dept of Agriculture	3016, 103c	7
Tongass NF	Coffman Road				Dept of Agriculture		2
Charleston National Marine Fisheries Service.	217 Fort Johnson Rd	Charleston	SC	29412	Dept of Commerce	3010	1
Monks Corner Army Air Force Depot.		Monks Corner	SC		Dept of Defense	103c	1
Usdoe Site 011 Power Plant.		Paducah	TN		Dept of Energy	103a	6
Usdoe Y–12 Plant/Mixed.	Bear Creek Road	Oak Ridge	TN	37831	Dept of Energy	103a	6
CG-Cape Canaveral Light.	9235 Grouper Rd	Cape Canaveral	FL	33131	Dept of Homeland Security.	3010	1
CG-Carysfort Reef Light.	100 Macarthur Causeway	Miami Beach	FL	33131	Dept of Homeland Security.	3010	1
CG-Hillsboro Light	Hillsboro Inlet	Pompano Beach	FL	33131	Dept of Homeland Security.	3010	4
CG-Sand Key Light	Cg Group Key W Trumbo Pt Annex.	Key West	FL	33131	Dept of Homeland Security.	3010	6
FWS-Wheeler National Wildlife Refuge.	2700 Refuge Headquarters Road.	Decatur	AL	35603–5202	Dept of Interior	3016, 103c	1
Charleston Harbor Site.		Charleston	SC		Dept of Interior	103c	6
Great Smoky Mtns Natl Park.	USNPS Rt 2	Gatlinburg	TN	37738	Dept of Interior	3005, 3010, 103c.	6
Schlegel Maryland Inc..	Bldg.115 Lynchburg Dr	Chestertown	MD	21620	Dept of Interior	3010	1
BIA Chinle Boarding School.	Hwy 191 15 Mi N of Chinle	Many Farms	AZ	86538	Dept of Interior	3010	4
Afton Canyon Union Pacific Railroad.			CA		Dept of Interior	3016	2
BLM-Afton Canyon Union Pacific Railroad.	Sections 13, 14, 18, 19, 20, 21 &22, T11N, R6E.	Newberry Springs	CA	92365	Dept of Interior	3016	2
Unicor Federal Prison Industries.	565 E Renfroe Rd	Talladega	AL	35160	Dept of Justice	3010	1
Tamiami International Flight Service Transmitter.	West of Chrome Avenue	Miami	FL		Dept of Transportation.	103a	2
FAA-Raleigh Durham International Airport.	Raleigh, NC	Raleigh	NC		Dept of Transportation.	103a	1
VA Medical Center	1 Freedom Way	Augusta	GA	30904	Dept of Veteran Affairs.	3010	1
National Air Radiation Environment Laboratory.	1504 Avenue A	Montgomery	AL	36115–2601	EPA	103c, 3010	1
US EPA Annex	79 T W Alexander Dr	Rtp	NC	27711	EPA	3010	6
Fairview Substation	Fairview Substation	Fairview	AL		Tennessee Valley Authority.	103a, 3010	1
Hanceville Substation.		Hanceville	AL		Tennessee Valley Authority.	103a	6
Muscle Shoals Garage.	Tva Reservation	Muscle Shoals	AL	35660	Tennessee Valley Authority.	3010, 103c	1
Trinity 500-Kv Substation.	Woodall Road at Ipeco Road	Decatur	AL	35801	Tennessee Valley Authority.	3010	1
TVA Hazardous Storage Facility.	Rt 2	Muscle Shoals	AL		Tennessee Valley Authority.	103a	6

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—DELETIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Boone Hydro Plant	TN Hwy 75/8 mi SE of	Kingsport	TN	37662	Tennessee Valley Authority.	103a, 3010 ..	6
Knoxville Garage ..	4216 Greenway	Knoxville	TN	37902	Tennessee Valley Authority.	103c, 3010, 3005.	4
Spring City Substation.	Highway 27	Spring City	TN		Tennessee Valley Authority.	103a	6
Tennessee Valley Authority.	Highway 69A	Big Sandy	TN	38221	Tennessee Valley Authority.	3010	4
Transportation Security Administration at Guam International Airport.	Chalan Pasaheru Street	Tamuning	GU	96913	Transportation Security Administration.	3010	1
Martin-Gadsden Air National Guard Station.	Gadsden Municipal Airport ..	Gadsden	AL		U.S. Air Force	103c, 3010 ..	2
Montgomery Air National Guard.	4600 S Richardson Rd, P.O. Box 250224.	Montgomery	AL	36108	U.S. Air Force	3016	2
Cape Canaveral Air Force Base.	6550 Abg/Deev	Patrick AFB	FL	32925	U.S. Air Force	3005, 3010, 3016, 103c, 103a.	6
Garden City Air National Guard Training Site.	Savannah International Airport.	Garden City	GA	31408	U.S. Air Force	3010	2
Savannah Air National Guard.	165 Alg, 1401 Robert B Miller Jr Dr, Savannah Iap.	Garden City	GA	31408	U.S. Air Force	3016	2
Kentucky Air National Guard Standiford Field.	1019 Old Grade Ln, 123 Aw/Em.	Louisville	KY	40213	U.S. Air Force	103c, 3016 ..	2
172nd Airlift Wing	141 Military Drive	Jackson	MS	39208	U.S. Air Force	3010	2
Donaldson Air Industrial Center.		Greenville	SC		U.S. Air Force	103c	2
164th Airlift Wing ..		Memphis	TN	37000	U.S. Air Force	3010	2
Mcghee Tyson Air National Guard Base.	Mcghee Tyson Airport	Knoxville	TN	37901	U.S. Air Force	103c, 3010, 3016.	2
Nashville Air National Guard.	240 Knapp Blvd	Nashville	TN	37217	U.S. Air Force	3016, 3010 ..	2
Utah Test And Training Range.	6.5 M. SE Of Wendover	Wendover	UT	89835	U.S. Air Force	103c	6
Onizuka Air Force Station.	6594 ABS/CC	Sunnyvale	CA	94088	U.S. Air Force	3010, 103c ..	3
Southern California Aviation.	18438 Readiness Street	Victorville	CA	92394	U.S. Air Force	3010	3
Space Launch Complex 4 East.	747 Nebraska Ave	Vandenberg AFB, San Diego.	CA	92101	U.S. Air Force	3010	3
Coosa River Storage Annex.	4 Miles NE Hwy 202	Talladega	AL	35160	U.S. Army	103c	7
Evans Army Reserve Center.	507 Westgage Parkway	Dothan	AL	36303	U.S. Army	3010	4
US Army Aviation Center Cairns.	Alabama Highway 85	Daleville	AL	36322–5000	U.S. Army	3010	6
USPFO For Kentucky.	120 Minuteman Pkwy (Bldg120).	Frankfort	KY	40601–6192	U.S. Army	3010, 103c ..	2
Camp Mccain National Guard.	P.O. Box 686	Elliott	MS	38926	U.S. Army	3010, 3016 ..	1
Fort Fisher Training Site.	Natl Grd Trng Center	Kure Beach	NC	28449	U.S. Army	3016	1
Wilmington Organizational Maintenance Shop #17.	1401 N Kerr Ave	Wilmington	NC	28405	U.S. Army	3016	1
Milan Utes	4 Miles South	Milan	TN	38350	U.S. Army	3016	6
Smyrna-Grubbs Kyle Training Site.	1 Mile North, Smyrna	Smyrna	TN	37167	U.S. Army	3016	2
Tullahoma Training Site.	One Mile East	Tullahoma	TN	37388	U.S. Army	3016	6
Soldier Support Center.	Building #28, Marion County	Fort Benjamin Harrison.	IN	46216	U.S. Army	3010	6
Newton Falls-Utes 1.	8 Miles Rte 2	Newton Falls	OH	44444	U.S. Army	3016	6

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—DELETIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Peoria Army Maintenance Support Activity 48G.	3523 W Farmington Rd	Peoria	IL	61604	U.S. Army	3010	3
Lawrenceville Coe-Chicago District.	P.O. Box 195, Route 4	Lawrenceville	IL	62439	U.S. Army	3010	6
Chicago District	Rte 100	Grafton	IL	62037	U.S. Army	3010	6
Middletown Organizational Maintenance Shop #3.	500 N Cross Street	Middletown	DE	19709	U.S. Army	3016	2
Milford Organizational Maintenance Shop #5A.	N Walnut Street	Milford	DE	19963	U.S. Army	3016	2
Armed Forces Institute of Pathology.	16050 Industrial Drive, Ste 100.	Gaithersburg	MD	20877	U.S. Army	3010	1
Olney	5115 Riggs Road	Olney	MD	20879	U.S. Army	3016	2
Greensburg Amsa 104 W.	2150 Hunter Road	Greensburg	PA	15601	U.S. Army	3010	1
Aafes Newport News District Center.	231 Enterprise Drive	Newport News	VA	23603	U.S. Army	3010	1
West Virginia (WV) Army National Guard.	Camp Dawson ATS	Kingwood	WV	25550	U.S. Army	103c	2
TCR Composites (Prev. Atk Space System).	530 West	Ogden	UT	84404	U.S. Army	3010	6
Cross Florida Barge Canal (Buckman Lock), Saj.	Near State Rt 40 At Canal	Palatka	FL	32177	U.S. Army Corps of Engineers.	3016	1
Greenup Lock And Dam.	5121 New Dam Road	Greenup	KY	41144	U.S. Army Corps of Engineers.	3010	1
Shelbiana Site	Route 1, Box 501	Shelbiana	KY	41562	U.S. Army Corps of Engineers.	3010	1
Arkabutla Lake Field Office.	Arkabutla Lake	Coldwater	MS	38618	U.S. Army Corps of Engineers.	3010	1
Grenada	Youngs Landing	Grenada	MS	38901	U.S. Army Corps of Engineers.	103a	1
Sardis Lake Field Office, Lmk.	Highway 315 (Rt 2, Box 500).	Sardis	MS	38668	U.S. Army Corps of Engineers.	3016	1
Nolf Barin Reid, Foley.		Foley	AL		U.S. Navy	103c	6
Jacksonville Naval Supply Center.	P.O. Box 26938	Jacksonville	FL	32226–6938	U.S. Navy	103c, 3005, 103a.	6
Naval Training Center, Orlando.	8th Street/NTC	Orlando	FL	32813	U.S. Navy	103	6
NTTC Cony Station		Pensacola	FL		U.S. Navy	103c	6
Saufley Field Netpsa.			FL		U.S. Navy	103c, 3010	6
USN Defense Property Disposal.	Naval Training Center	Orlando	FL	32813	U.S. Navy	3010	6
Naval Support Activity Mid-South (Brac Nas Memphis).	5722 Integrity Drive	Millington	TN	38054–5045	U.S. Navy	3005, 3010, 3016, 103c,103a.	6
Charleston Postal Service.	602 Donnelly St	Charleston	WV	25301	U.S. Postal Service.	3010	1
Cave Run Lake	Bridge at Cave Run Lake	Morehead	KY	40351	UNKNOWN	3010	4
Iaeger Pcb Site	Near Lick Branch	Iaeger	WV		UNKNOWN	103c	2

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—CORRECTIONS

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Smithsonian Inst-Natural History Bldg.	10th & Constitution Avenue NW.	Washington	DC	20560	*** Unknown ***	RCRA 3010.	

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—CORRECTIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Smithsonian Inst-Natural History Bldg.	10th & Constitution Avenue NW.	Washington	DC	20560	Smithsonian Board of Regents.	RCRA 3010	21
Catron County Shooting Range.	PO Box 170	Reserve	NM	87830	Agriculture-Forest Service.	RCRA 3010.	
Gila National Forest: Catron County Shooting Range—Reserve.	PO Box 170	Reserve	NM	87830	Department of Agriculture.	RCRA 3010	21
Gila National Forest.	Forest Route 701 3.5 Mi E of Hwy 180.				Agriculture.		
Gila National Forest: Mineral Creek Tailing.	Forest Route 701 3.5 Mi E of Hwy 180.				Department of Agriculture.		20A
King Edward Mine	18 Mi NW of Blanding	Blanding	UT	84511	Agriculture-Forest Service.	CERCLA 103.	
King Edward Mine	18 Mi NW of Blanding	Blanding	UT	84511	Department of Agriculture.	CERCLA 103	21
USDA FS Boise Nf: Belshazzar Mine.	Granite Creek Road, 3 Mi W of Placerville, T7N R4E Sec 17, Boise Meridian.	Placerville	ID	83666	Agriculture-Forest Service.	Other.	
USDA FS Boise Nf: Belshazzar Mine.	Granite Creek Road, 3 Mi W of Placerville, T7N R4E Sec 17, Boise Meridian.	Placerville	ID	83666	Department of Agriculture.	Other	21
USDA FS Caribou-Targhee Nf: Smoky Canyon Mine Site.	Smoky Canyon Rd/Fs Rd 110, 24 Mi E of Soda Springs, T8S R45E Sec 24, 25 & 36; T8S R46E Sec 17, 18, 1.	Soda Springs	ID	83276	Agriculture-Forest Service.	Other.	
USDA FS Caribou-Targhee Nf: Smoky Canyon Mine Site.	Smoky Canyon Rd/Fs Rd 110, 24 Mi E of Soda Springs, T8S R45E Sec 24, 25 & 36; T8S R46E Sec 17, 18, 1.	Soda Springs	ID	83276	Department of Agriculture.	Other	21
USDA FS Mt. Baker-Snoqualmie Nf: Rainy Mine & Mill Site.	Fs Rd 5640, 12 Mi NE of North Bend, T24N R10E Sec 9 & 16, Willamette Meridian.	North Bend	WA	98045	Agriculture-Forest Service.	Other.	
USDA FS Mt. Baker-Snoqualmie Nf: Rainy Mine & Mill Site.	Fs Rd 5640, 12 Mi NE of North Bend, T24N R10E Sec 9 & 16, Willamette Meridian.	North Bend	WA	98045	Department of Agriculture.	Other	21
Camp Lonely Landfill Site.	Pitt Point, 1 Mi W of Pt. Lonely, W Edge of Gravel Path, T18N R5W, Sec18 Se1/4, Umiat Meridian.	Niuiqsuit	AK	99789	USda-Fs	RCRA 3010.	
Camp Lonely Landfill Site.	Pitt Point, 1 Mi W of Pt. Lonely, W Edge of Gravel Path, T18N R5W, Sec18 Se1/4, Umiat Meridian.	Niuiqsuit	AK	99789	Department of Interior.	RCRA 3010	21
Opheim Radar Station.	2 Miles West of Opheim	Opheim	MT	59250	*** Unknown ***	CERCLA 103.	
Opheim Radar Station.	2 Miles West of Opheim	Opheim	MT	59250	US Air Force	CERCLA 103	21
Pease Air Force Base.	509 Csg/Cc	Portsmouth	NJ	03801	Air Force	RCRA 3005.	
Pease Air Force Base.	509 Csg/Cc	Portsmouth	NH	03801	US Air Force	RCRA 3005	20A
U.S. Defense Fuel Support Support Point.	Trundy Road Box 112	Searsport	ME	04974	Defense Logistics Agency.	RCRA 3010.	
U.S. Defense Fuel Support Point.	Trundy Road Box 112	Searsport	ME	04974	Defense Logistics Agency.	RCRA 3010	21
Defense National Stockpile Center.	710 Ordinance Rd	Baltimore	MD	21226	Defense Logistics Agency.	RCRA 3005.	
Former Curtis Bay Depot.	710 Ordnance Rd	Baltimore	MD	21226	Defense Logistics Agency.	RCRA 3005	21
Defense Depot Memphis.	2163 Airways Blvd	Memphis	TN	38114	Defense Logistics Agency.	RCRA 3005.	

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—CORRECTIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Defense Depot Memphis.	2163 Airways Blvd	Memphis	TN	38114	U.S. Army	RCRA 3005	21
Ogden Defense Depot.	500 West 12th Street	Ogden	UT	84407–5000	Defense Logistics Agency.	RCRA 3016.	
Ogden Defense Depot.	500 West 12th Street	Ogden	UT	84407–5000	U.S. Army	RCRA 3016	21
NGA?-Bethesda	4600 Sangamore Road	Bethesda	MD	20816	National Geospatial.	RCRA 3010.	
NGA-Bethesda	4600 Sangamore Road	Bethesda	MD	20816	Department of Defense.	RCRA 3010	22
NGA-Washington Navy Yard.	1st St & M St. SE	Washington	DC	20374	National Geospatial.	RCRA 3010.	
NGA-Washington Navy Yard.	1st St & M St. SE	Washington	DC	20374	Department of Defense.	RCRA 3010	21
NGA-St. Louis	3200 S. Second Street	St. Louis	MO	63118	National Geospatial.	RCRA 3010.	
NGA-St. Louis	3200 S. Second Street	St. Louis	MO	63118	Department of Defense.	RCRA 3010	21
NGA-St. Louis	8900 S. Broadway	St. Louis	MO	63118	National Geospatial.	RCRA 3010.	
NGA-St. Louis	8900 S. Broadway	St. Louis	MO	63118	Department of Defense.	RCRA 3010	21
Job Corps Center-St Louis.	E Natural Bridge Ave & Goodfellow Blvd.	St Louis	MO	63120	*** Unknown ***	CERCLA 103.	
Job Corps Center-St Louis.	E Natural Bridge Ave & Goodfellow Blvd.	St Louis	MO	63120	Department of Labor.	CERCLA 103	21
Old Saint Louis Base.	Foot of Iron St. & Mississippi River.	St Louis	MO	63111	Homeland Security-Coast Guard.	CERCLA 103.	
USCG Old Saint Louis Base.	Foot of Iron St. & Mississippi River.	St Louis	MO	63111	Department of Homeland Security.	CERCLA 103	21
USHS CG Burrows Island Light Station.	SW Side of Burrows Island, 5 Mi SW of Anacortes.	Anacortes	WA	98221	Homeland Security-Coast Guard.	RCRA 3010.	
USCG Burrows Island Light Station.	SW Side of Burrows Island, 5 Mi SW of Anacortes.	Anacortes	WA	98221	Department of Homeland Security.	RCRA 3010	21
Manchester Housing and Development Authority.	83 Trahan Street	Manchester	NH	03103	*** Unknown ***	RCRA 3010.	
Manchester Housing and Development Authority.	83 Trahan Street	Manchester	NH	03103	Housing and Urban Development.	RCRA 3010	21
USDOI BIA Signal Peak Ranger Station.	Bia 140 Rd-Signal Peak Road, 24 Mi SW of White Swan, T9N R13E Sec 25, Willamette Meridian.	White Swan	WA	98952	Interior-Bureau of Indian Affairs.	RCRA 3010.	
USDOI BIA Signal Peak Ranger Station.	Bia 140 Rd-Signal Peak Road, 24 Mi SW of White Swan, T9N R13E Sec 25, Willamette Meridian.	White Swan	WA	98952	Department of Interior.	RCRA 3010	21
BLM Eagle County Landfill.	T.4. N.R.83.W. Sec.10 & 11	Eagle	CO	81613	Interior-Bureau of Land Management.	CERCLA 103.	
BLM Eagle County Landfill.	T.4. N.R.83.W. Sec.10 & 11	Eagle	CO	81613	Department of Interior.	CERCLA 103	21
BLM Fremont	T.48.N.R.12.E. Sec.19	Cotopaxi	CO	81223	Interior-Bureau of Land Management.	CERCLA 103.	
BLM Fremont	T.48.N.R.12.E. Sec.19	Cotopaxi	CO	81223	Department of Interior.	CERCLA 103	21
BLM Illegal Airstrip John Greytak.	Section 6 T.11N.R.27.E	Flatwillow	MT	59059	Interior-Bureau of Land Management.	CERCLA 103.	
BLM Illegal Airstrip John Greytak.	Section 6 T.11N.R.27.E	Flatwillow	MT	59059	Department of Interior.	CERCLA 103	21
BLM Kremmling Dump.	T.1.N.R.80.E. Sec.9	Kremmling	CO	80459	Interior-Bureau of Land Management.	CERCLA 103.	
BLM Kremmling Dump.	T.1.N.R.80.E. Sec.9	Kremmling	CO	80459	Department of Interior.	CERCLA 103	21

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—CORRECTIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
BLM Roundup Landfill.	1.5 Miles Northwest of Roundup.	Roundup	MT	59072	Interior-Bureau of Land Management.	CERCLA 103.	
BLM Roundup Landfill.	1.5 Miles Northwest of Roundup.	Roundup	MT	59072	Department of Interior.	CERCLA 103	21
BLM San Miguel Landfill #1.	T.44.N.R.15.W. Sec.26	Naturita	CO	81422	Interior-Bureau of Land Management.	CERCLA 103.	
BLM San Miguel Landfill #1.	T.44.N.R.15.W. Sec.26	Naturita	CO	81422	Department of Interior.	CERCLA 103	21
BLM Sluice Gulch Leaking Adit.	T.6.Sr.15.W. Sec.5	Phillipsburg	MT	59858	Interior-Bureau of Land Management.	CERCLA 103.	
BLM Sluice Gulch Leaking Adit.	T.6.Sr.15.W. Sec.5	Phillipsburg	MT	59858	Department of Interior.	CERCLA 103	21
BLM Steamboat Point.	T.25.N.R.10.E. Sec.18 Pmm	Loma	MT	59460	Interior-Bureau of Land Management.	CERCLA 103.	
BLM Steamboat Point.	T.25.N.R.10.E. Sec.18 Pmm	Loma	MT	59460	Department of Interior.	CERCLA 103	21
BLM-Maybell Dump.	6 Mi East of Maybell	Maybell	CO	81640	Interior-Bureau of Land Management.	CERCLA 103.	
BLM-Maybell Dump.	6 Mi East of Maybell	Maybell	CO	81640	Department of Interior.	CERCLA 103	21
BLM-Montrose County Dump.	4 Mi NE Montrose T48N R19W Sec22.	Montrose	CO	81401	Interior-Bureau of Land Management.	CERCLA 103.	
BLM-Montrose County Dump.	4 Mi NE Montrose T48N R19W Sec22.	Montrose	CO	81401	Department of Interior.	CERCLA 103	21
BLM Chaffee County Landfill.	T.51.N.R.8.E. Sec.21, U.S. Hwy 285 10M North of Salida.	Salida	CO	81201	Interior-Bureau of Land Management.	CERCLA 103.	
BLM Chaffee County Landfill.	T.51.N.R.8.E. Sec.21, U.S. Hwy 285 10M North of Salida.	Salida	CO	81201	Department of Interior.	CERCLA 103	21
Kelly Silver Mine	Hwy 395	Red Mountain	CA	93558	Interior-Bureau of Land Management.	CERCLA 103.	
Kelly Silver Mine	Hwy 395	Red Mountain	CA	93558	Department of Interior.	CERCLA 103	21
Pond Mine	Sec 3, T12N R10E Mdbm	Forest Hill	CA	95631	Interior-Bureau of Land Management.	CERCLA 103.	
Pond Mine	Sec 3, T12N R10E Mdbm	Forest Hill	CA	95631	Department of Interior.	CERCLA 103	21
Poore Mine	Benedict Canyon Lane	Nevada Co	CA		Interior-Bureau of Land Management.	CERCLA 103.	
Poore Mine	Benedict Canyon Lane	Nevada Co	CA		Department of Interior.	CERCLA 103	21
USDOI BLM Idora Mine and Mill Site.	Carbon Center Road, 10 Mi SE of Pritchard, 10 Mi N of Wallace, T49N R5E Sec 30.	Wallace	ID	83873	Interior-Bureau of Land Management.	Other.	
USDOI BLM Idora Mine and Mill Site.	Carbon Center Road, 10 Mi SE of Pritchard, 10 Mi N of Wallace, T49N R5E Sec 30.	Wallace	ID	83873	Department of Interior.	Other	21
Overton Gravel Pit Trespass Site.	1/4 Mi W of Hwy 169	Overton	NV	89040	Interior-Bureau of Reclamation.	RCRA 3010.	
Overton Gravel Pit Trespass Site.	1/4 Mi W of Hwy 169	Overton	NV	89040	Department of Interior.	RCRA 3010	21
USDOI Br Hazardous Waste Site.	T19N R23E Sec 31, Willamette Meridian, 25 Mi W of George, 35 Mi SW of Quincy.	Quincy	WA	98848	Interior-Bureau of Reclamation.	RCRA 3010.	
BR Quincy Illegal Dump Site.	T19N R23E Sec 31, Willamette Meridian, 25 Mi W of George, 35 Mi SW of Quincy.	Quincy	WA	98848	Department of Interior.	RCRA 3010	22

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—CORRECTIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
US Geological Survey-Marine Facility (Marfac).	599 Seaport Blvd	Redwood City	CA	94063	USDOI–BLM	RCRA 3010.	
US Geological Survey-Marine Facility (Marfac).	599 Seaport Blvd	Redwood City	CA	94063	Department of Interior.	RCRA 3010	21
National Park Svc/De Water Gap.	Pioneer Trail	Pahaquarry	NJ	07825	NPS	RCRA 3010.	
National Park Svc/De Water Gap.	Pioneer Trail	Pahaquarry	NJ	07825	Department of Interior.	RCRA 3010	21
FBI Academy	15 Hogans Alley	Quantico	VA	22135	FBI	RCRA 3010.	
FBI Academy	15 Hogans Alley	Quantico	VA	22135	Department of Justice.	RCRA 3010	21
Transportation Security Administration.	300 Rogers Blvd	Honolulu	HI	96819	Treasury	RCRA 3010.	
Transportation Security Administration.	300 Rogers Blvd	Honolulu	HI	96819	Department of Homeland Security.	RCRA 3010	21
IRS Philadelphia Service Center.	11601 Roosevelt Blvd	Philadelphia	PA	19255	*** Unknown ***	RCRA 3010.	
IRS Philadelphia Service Center.	11601 Roosevelt Blvd	Philadelphia	PA	19255	Department of Treasury.	RCRA 3010	21
IRS-Washington	1111 Constitution Ave, NW	Washington	DC	20032	*** Unknown ***	CERCLA 103.	
IRS-Washington	1111 Constitution Ave, NW	Washington	DC	20032	Department of Treasury.	CERCLA 103	21
United States Mint	155 Herman Street	San Francisco	CA	94102	*** Unknown ***	RCRA 3010.	
United States Mint	155 Herman Street	San Francisco	CA	94102	Department of Treasury.	RCRA 3010	21
Bureau of Engraving and Printing Western Currency Facility.	9000 Blue Mound Rd-1 Mile South Fm.	Fort Worth	TX	76131	*** Unknown ***	RCRA 3010.	
Bureau of Engraving and Printing Western Currency Facility.	9000 Blue Mound Rd-1 Mile South Fm.	Fort Worth	TX	76131	Department of Treasury.	RCRA 3010	21
Bureau of Engraving & Printing.	14Th & C Sts SW	Washington	DC	20228	*** Unknown ***	RCRA 3005.	
Bureau of Engraving & Printing.	14Th & C Sts SW	Washington	DC	20228	Department of Treasury.	RCRA 3005	21
Urbandale Bulk Mail Center.	4000 NW 109th Street	Urbandale	IA	50395	*** Unknown ***	RCRA 3016.	
Urbandale Bulk Mail Center.	4000 NW 109th Street	Urbandale	IA	50395	US Postal Service	RCRA 3016	21
U.S. Postal Service	135 A Street	Boston	MA	02210	*** Unknown ***	RCRA 3010.	
U.S. Postal Service	135 A Street	Boston	MA	02210	US Postal Service	RCRA 3010	21
U.S. Postal Service Incoming Mail Center.	307 Becham St	Chelsea	MA	02150	*** Unknown ***	CERCLA 103.	
U.S. Postal Service Incoming Mail Center.	307 Becham St	Chelsea	MA	02150	US Postal Service	CERCLA 103	21
USPS Vehicle Maint Fac Fairbanks.	5400 Mail Trail Way	Fairbanks	AK	99709	*** Unknown ***	RCRA 3010.	
USPS Vehicle Maint Fac Fairbanks.	5400 Mail Trail Way	Fairbanks	AK	99709	US Postal Service	RCRA 3010	21
US Postal Service	5800 W Century Blvd	Los Angeles	CA	90009	*** Unknown ***	RCRA 3010.	
US Postal Service	5800 W Century Blvd	Los Angeles	CA	90009	US Postal Service	RCRA 3010	21
USPS Hillcrest Station.	300 E Hillcrest Blvd	Inglewood	CA	90301–9998	*** Unknown ***	RCRA 3010.	
USPS Hillcrest Station.	300 E Hillcrest Blvd	Inglewood	CA	90301–9998	US Postal Service	RCRA 3010	21
US Postal Service Vehicle Maintenance.	60 W Oliver St	Baltimore	MD	21201	*** Unknown ***	RCRA 3010.	
US Postal Service Vehicle Maintenance.	60 W Oliver St	Baltimore	MD	21201	US Postal Service	RCRA 3010	21

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #28—CORRECTIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
North Charleston Post office.	0.7 Mile North of Aviation	North Charleston	SC	29410	*** Unknown ***	CERCLA 103.	
North Charleston Post office.	0.7 Mile North of Aviation	North Charleston	SC	29410	US Postal Service	CERCLA 103	21
US Postal Service Bacon Station.	Stratford Dr	Bloomingdale	IL	60117–7000	*** Unknown ***	RCRA 3010.	
US Postal Service Bacon Station.	Stratford Dr	Bloomingdale	IL	60117–7000	US Postal Service	RCRA 3010	21
US Postal Service Vehicle Maintenance Facility.	Stratford Dr	Bloomingdale	IL	60117–7000	*** Unknown ***	RCRA 3010.	
US Postal Service Vehicle Maintenance Facility.	Stratford Dr	Bloomingdale	IL	60117–7000	US Postal Service	RCRA 3010	21
Aurora Post office Site (New).	N Broadway (Rt. 25) and Indiana Circle.	Aurora	IL	60505	*** Unknown ***	CERCLA 103.	
Aurora Post office Site.	N Broadway (Rt. 25) and Indiana Circle.	Aurora	IL	60505	US Postal Service	CERCLA 103	22
Madison Post office.	3902 Milwaukee St	Madison	WI	53714	*** Unknown ***	RCRA 3010.	
Madison Post office.	3902 Milwaukee St	Madison	WI	53714	US Postal Service	RCRA 3010	21
Minneapolis St. Paul Bulk Mail Center.	3165 S. Lexington Ave	St. Paul	MN	55121	*** Unknown ***	RCRA 3010.	
Minneapolis St. Paul Bulk Mail Center.	3165 S. Lexington Ave	St. Paul	MN	55121	US Postal Service	RCRA 3010	21
Monroe Post office	210 W Front St	Monroe	MI	48161	*** Unknown ***	RCRA 3010.	
Monroe Post office	210 W Front St	Monroe	MI	48161	US Postal Service	RCRA 3010	21
Campbell Postal Service.	1587 Dell Avenue	Campbell	CA	95006	*** Unknown ***	CERCLA 103.	
Campbell Postal Service.	1587 Dell Avenue	Campbell	CA	95006	US Postal Service	CERCLA 103	21
City of Industry Postal Service.	15421 E. Gale Ave	City of Industry	CA	91745	*** Unknown ***	CERCLA 103.	
City of Industry Postal Service.	15421 E. Gale Ave	City of Industry	CA	91745	US Postal Service	CERCLA 103	21
Herbert C. Hoover Building (Aka: Main Commerce)..	1401 Constitution Ave. NW, Room 7603.	Washington	DC	20230	Dept of Commerce	3010.	
Herbert C. Hoover Building (Aka: Main Commerce)..	1401 Constitution Ave. NW, Room 7603.	Washington	DC	20230	General Services Administration.	3010	21
Arlington Defense Printing Service office.	Rmbe 854 The Pentagon	Arlington	VA	20301	Army	3010.	
Pentagon	Pentagon Reservation	Arlington	VA	22204	Department of Defense.	3010	21
Allegheny National Forest.	222 Liberty Street Box 847 ..	Warren	PA	16365	Department of Agriculture.	103(c), 3016.	
Allegheny National Forest—McKinley Tar Pits.	Township Road 317, .5 mile east of Rte. 66.	Kane	PA	16735	Department of Agriculture.	103(c), 3016	20A

[FR Doc. 2015–20248 Filed 8–14–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 2015–19667) published on pages 48103 and 48104 of the issue for Tuesday, August 11, 2015.

Under the Federal Reserve Bank of Minneapolis heading, the entry for *The Fishback Annuity Trust I, the Fishback Annuity Trust II, the Fishback Annuity Trust VI, Patricia S. Fishback, individually and as voting trustee of the trusts, all of Brookings, South Dakota, William Cornick Stephen Fishback, Francesca Margaret Fishback, both of San Francisco, California; Abby*

Margaret Rivlin, and Toby Sebastian Rivlin, both of Madison, Wisconsin; to retroactively join the Fishback Family Control group, is revised to read as follows:

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Fishback Annuity Trust I, the Fishback Annuity Trust II, the Fishback Annuity Trust VI, Patricia S. Fishback, individually and as voting trustee of the trusts, all of Brookings, South Dakota, William Fishback, San Francisco, California, Francesca Fishback, San Francisco, California, Abby Rivlin, Madison, Wisconsin, Toby Rivlin, Madison, Wisconsin, and Fishback Grandchildren Trust I,* Brookings, South Dakota, First Bank & Trust, Brookings, South Dakota, trustee, to retroactively join the Fishback Family Control group which controls 25 percent or more of the shares of Fishback Financial Corporation, Brookings, South Dakota and indirectly control First Bank & Trust, Brookings, South Dakota, First Bank & Trust, N.A., Pipestone, Minnesota, First Bank & Trust, Sioux Falls, South Dakota, and First Bank & Trust of Milbank, Milbank, South Dakota.

Comments on this application must be received by August 25, 2015.

Board of Governors of the Federal Reserve System, August 12, 2015.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2015–20180 Filed 8–14–15; 8:45 am]

BILLING CODE 6210–01–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 August 31, 2015.

A. Federal Reserve Bank of Cleveland (Nadine Wallman, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. *Jeffrey Joseph Woda, Columbus, Ohio, and David Cooper, Jr.,* Gahanna, Ohio, individually and as a group acting in concert, to acquire additional voting shares of Benchmark Bancorp, Inc., and thereby indirectly acquire additional voting shares of Benchmark Bank, both in Gahanna, Ohio.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Joanne E. Matthews,* individually and as trustee of Haviland Bancshares, Inc. Employee Stock Ownership Plan, Leawood, Kansas, to acquire additional voting shares of Haviland Bancshares, Inc., and thereby indirectly acquire additional voting shares of The Haviland State Bank, both in Haviland, Kansas; and Stanley E. Robertson, Greensburg, Kansas, to retain voting shares of Haviland Bancshares, Inc., and thereby indirectly retain voting shares of the Haviland State Bank, both in Haviland, Kansas.

Board of Governors of the Federal Reserve System, August 11, 2015.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2015–20176 Filed 8–14–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act; Notice of Meeting

TIME AND DATE: 10:00 a.m. (Eastern Time) August 24, 2015 (Telephonic).

PLACE: 10th Floor Board Meeting Room, 77 K Street NE., Washington, DC 20002.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

Open Session

1. Approval of the Minutes of the July 27, 2015 Board Member Meeting
2. Monthly Reports
(a) Monthly Participant Activity Report
(b) Legislative Report
(c) Investment Policy Report
3. Quarterly Metrics Report
4. Calendar Review: 2015 and 2016

CONTACT PERSON FOR MORE INFORMATION: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

Dated: August 12, 2015.

James Petrick,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2015–20231 Filed 8–13–15; 4:15 pm]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–15–15AFJ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

The Green Housing Pilot Study (New Orleans)—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) seeks a new three-year OMB approval for the Green Housing Pilot Study (New Orleans) or ''Pilot'' of additional components to be tested at the New Orleans site for the main Green Housing Study (OMB No. 0920–0906, Expiration 10/31/2017). The goal of the Pilot is to apply novel approaches to study exposures to various indoor pollutants in children ranging in age from newborn–12 years. The information collected will help scientists better understand time-activity patterns of children that affect exposures to chemical and biological agents in their residential environments, and improve estimates of exposure for children.

Results from this Pilot will inform future Green Housing Study sites and will potentially reduce participant time burden by collecting some questionnaires electronically. This study directly supports the Healthy People 2020 Healthy Homes' health protection goal of the CDC. This investigation is consistent with CDC's Health Protection Research Agenda, which calls for research to identify the major environmental causes of disease and disability and related risk factors.

In 2011, CDC funded the first two study sites for the Green Housing Study, Boston and Cincinnati. In these two cities, renovations sponsored by the Department of Housing and Urban Development (HUD) had already been scheduled. By selecting sites in which renovations were already scheduled to occur, CDC has leveraged the opportunity to collect survey and biomarker data from residents, and to collect environmental measurements in homes to evaluate associations between green housing and health.

Several objectives will be evaluated during the Pilot:

(1) Identify and characterize factors affecting children's exposures to chemical ingredients from consumer products found in their everyday environment to support the data and modeling needs of the exposure components of EPA's national research programs;

(2) Evaluate the Pilot data metrics for incorporation in and enhancement of CDC's ability to understand the relationship between environmental exposures and asthma;

(3) Compare multimedia measurements and survey data between pre- and post-renovation time points in green and non-green low-income housing to assess exposure related changes in the residence and participants due to renovation activities.

Like the other Green Housing Study sites, data will be collected from 64 households. Study participants are children with asthma and their mothers/primary caregivers living in HUD-subsidized housing that has either received a green renovation or is a non-green home. This Pilot will also enroll younger children with a focus on newborns–3 years. Having a larger age range of children in the study will improve the estimates of how environmental exposures inside and outside of their homes can occur during different life stages of childhood, a critical period of life when the immune system and other organ systems are still developing.

The Pilot will be implemented by incorporating it into the Green Housing study schedule. Data collection methods include: (1) Time-activity pattern questionnaire of children, administered to mothers/primary caregivers; (2) collection of air, soil, dust samples from the respondent's home; and (3) collection of blood, urine, toenails clippings, and feces from the respondent's eligible children.

We hypothesize that a better estimation of exposure pathways will improve exposure modeling for the current and the future Green Housing Study sites, and influence future research in environmental health. Although children are considered participants, the respondents to all questionnaires are the mothers/primary caregivers; no children will fill out questionnaires.

The respondents are 64 mothers/primary caregivers of enrolled children; or approximately 21 respondents each year. There is no cost to the respondents other than their time to participate in the study.

The total estimated annual burden hours for the Pilot is 56 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Mothers/Primary Caregivers of Enrolled Children.	Time/Activity Questionnaire	21	4	40/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–20191 Filed 8–14–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974: Report of New System of Records

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS)

ACTION: Notice of New System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new SOR titled, ''CMS Risk Adjustment Suite of Systems (RASS),'' System No. 09–70–0508. Payments to Medicare Advantage (MA) organizations, Part D sponsors, and Program of All Inclusive Care for the Elderly (PACE) organizations (collectively referred to as ''MA organizations and other entities'') are adjusted based on the health status of enrolled Medicare beneficiaries (''enrollees''). RASS is established to receive, process, and store the data used

to risk-adjust payments based on enrollee health status. The data will be used specifically to develop risk adjustment models and to calculate the risk score for each enrollee.

Each MA organization and other entity must submit data to CMS in accordance with CMS regulations and instructions. ''Risk adjustment data'' refers to data submitted in two separate formats: comprehensive data equivalent to Medicare fee-for-service data (often referred to as encounter data); and data in abbreviated formats (often referred to as RAPS data). The MA risk adjustment data addressed by this SOR includes RAPS data submitted by a MA organization in an abbreviated format, as referenced at § 422.310(d)(1), and similar abbreviated risk adjustment data submitted by other MA organizations and other entities. Encounter data has a separate SOR (System No. 09–70–0506).

DATES: Effective 30 days after publication. Written comments should be submitted on or before the effective date. HHS/CMS/CM may publish an amended system of records notice (SORN) in light of any comments received.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Security, Privacy Policy & Governance, Information Security & Privacy Group, Office of Enterprise Information, CMS, 7500 Security Boulevard, Baltimore, MD 21244–1870, Mailstop: N1–24–08, Office: (410) 786–5357, email: *walter.stone@cms.hhs.gov.* Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., Eastern Time zone.

FOR FURTHER INFORMATION CONTACT: Risk Adjustment Mailbox Coordinator, Division of Encounter Data and Risk Adjustment Operations, Medicare Plan Payment Group, Center for Medicare, CMS, Mail Stop C1–13–07, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The email is *Riskadjustment@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Risk Adjustment Suite of Systems (RASS)

The new RASS system of records is being established to cover data used to create risk adjustment scores needed to risk-adjust payments to Medicare and Medicaid provider entities, based on beneficiary demographics and health status. Risk-adjusted payments will implement reformatory provisions of the Social Security Act at sections 1853(a), 1860D–15(c), and 1894(d)(2) (42 U.S.C. 1395w–23, 1395w–115, and 1395eee), intended to collect and accurately calculate scores based on a beneficiary's demographics and health status. RASS will cover data housed in two existing information systems: The Risk Adjustment Processing System (RAPS), and the Risk Adjustment System (RAS). RAS will contain data extracted from RAPS and from two other IT systems (CME and NMUD), as more fully explained below:

- *RAPS* will receive abbreviated current risk adjustment data, consisting of diagnosis data about each beneficiary and the beneficiary's health care provider type, submitted by the relevant payee entity through the Front-End Risk Adjustment System (FERAS); RAPS will use the data to create an enrollee diagnosis data file for each beneficiary (See Categories of Records for data elements).
- *RAS* will extract the enrollee diagnosis data files from RAPS and will receive current demographic, enrollment and diagnoses data and past medical history data for each enrollee from two other CMS systems (CME and NMUD); RAS will use the RAPS, CME, and NMUD data to calculate risk factors and create a Risk Adjustment Factor (RAF) file, containing the risk score of each beneficiary:
  - *Common Medicare Environment (CME):* RAS will extract current individual demographic and enrollment data about each enrollee (See Categories of Records for data elements).
  - *National Claims History files housed in the National Medicare Utilization Database (NMUD):* RAS will extract current Medicare Fee-for-service (FFS) diagnoses information submitted on Inpatient, Outpatient, and Physician claims for each enrollee (See Categories of Records for data elements).
- RAS will transmit the Risk Adjustment Factor (RAF) file created in RAS to CMS' payment processing system for purposes of calculating and adjusting payments to payee entities, as follows:
  - CMS pays MA organizations on a monthly prospective amount for each beneficiary enrolled (enrollee) in a Part C plan.
  - CMS pays Part D sponsors a monthly prospective amount that reflects the plan sponsor's estimate of the revenue needed to cover a plan's costs for the risk portion of basic prescription drug coverage. The direct subsidy is adjusted based on the beneficiary's risk score, which reflects expected prescription drug expenditures for the coverage year (relative to a national average of 1.0), based on demographic and health status information for that person.
  - CMS pays PACE organizations a monthly capitation amount based on the Part A and Part B payment rates established for purposes of payment to Medicare Advantage organizations pursuant to 1894(d)(2). CMS will ensure that payments take into account the comparative frailty of PACE enrollees relative to the general Medicare population.

In addition to providing the file used to calculate risk adjustment payments, the RASS also provides reports for CMS based on the analysis of RAF files and other criteria; these reports include MA plan file submission transactions (acceptance rates, rejection rates, error rates, etc.) on a daily, weekly, monthly, and quarterly basis.

II. The Privacy Act

The Privacy Act governs the collection, maintenance, use, and dissemination of certain information about individuals by agencies of the Federal Government.

A ''SOR'' is a group of any records under the control of a Federal agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** notice of the existence and character of each SOR that the agency maintains. The System of Records Notice (SORN) identifies or describes the laws authorizing the system to be maintained; the types and sources of records in the system; the categories of individuals to whom the records pertain; the purposes for which the records are used within the agency; the routine uses for which a record maybe disclosed to parties outside the agency without the individual's prior, written consent; agency policies and procedures for safeguarding, storing, retrieving, accessing, retaining, and disposing of the records; the procedures for an individual to follow to make notification, access, and amendment requests to the System Manager; and whether the SOR is exempt from certain Privacy Act requirements.

System Number:

09–70–0508

SYSTEM NAME:

CMS Risk Adjustment Suite of Systems (RASS), HHS/CMS/CM.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

RASS (RAS/RAPS) Location: CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Information collected and maintained in this system pertains to: (1) Medicare beneficiaries enrolled in a Part C MA plan, MA–PD plan, PDP or PACE organization (''enrollees'') and (2) the health care provider(s), supplier(s), physician(s), or other practitioner(s) (''Providers'') who provide health care items and services to these enrollees.

CATEGORIES OF RECORDS IN THE SYSTEM:

The MA plans, MA–PDs, PDPs and PACE organizations (''MA organizations and other entities'') receive the data from the providers which is then submitted to RAPS via FERAS. The data received from the MA organizations and other entities are primarily diagnosis data extracted from claims information. Additional FFS and utilization data regarding those submissions are received from the CME and NCH data systems to complete the enrollee data requirements.

Records will consist of the risk score for each enrollee and the data used to calculate the score, contained in Risk Adjustment Factor (RAF) files created in CMS' Risk Adjustment System (RAS), using data extracted from three other CMS IT systems:

- *RAPS data:* Diagnosis data files containing abbreviated current diagnosis data submitted by payee entities to CMS's Risk Adjustment Processing System (RAPS):
  - Health Insurance Claim Number (HICN)
  - Provider Type
  - Service From Date
  - Service Through Date
  - Plan Number (MAO contract number)
  - Diagnosis Code
  - Diagnosis Delete Date
  - RAS Diagnosis Indicator
  - NCH Category Equitable BIC
  - Accrete Data
  - Delete Plan Number
  - Submitter ID
  - Daily File Code, and
  - Delete File Code
- *CME data:* Current demographic and enrollment data from CMS's Common Medicare Environment (CME):
  - Beneficiary Link Key Partition number
  - Beneficiary Link Identifier
  - Health Insurance Claim Number (HICN)
  - Beneficiary Social Security Number
  - Beneficiary Birth Date
  - Beneficiary Death Date
  - Beneficiary Sex Code
  - Beneficiary Race Code
  - Beneficiary First Name
  - Beneficiary Middle Name
  - Beneficiary Last Name
- *NCH data:* Current diagnosis data [and past medical history data] from National Claims History Files in CMS's National Medicare Utilization Database (NMUD):
  - Health Insurance Claim Number (HICN)
  - NCH Category Equitable BIC
  - Diagnosis code
  - Service Through Date
  - Service From Date
  - Beneficiary Link Identifier
  - Provider Number

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

This system was established pursuant to sections 1853(a), 1860D–15(c), and 1894(d)(2)of the Social Security Act (42 U.S.C. 1395w–23, 1395w–115, 1395eee).

PURPOSE(S) OF THE SYSTEM:

Records will be used within the agency to develop risk adjustment models and to calculate the risk score for each Medicare beneficiary enrolled in the Medicare health plan. The risk score will be reported to the system that CMS uses to process payments, and ultimately will be used to adjust payments to MA organizations, Part D sponsors, and PACE organizations, based on beneficiary health status. (Note that payment records are not covered under this system of records.)

Information retrieved from this SOR will be used for the following purposes:

- To determine the risk adjustment factors used to adjust payments to MA organizations and other entities, as required under 42 CFR 422.304(a) and (c), 423.329 and 460.180
- to update risk adjustment models
- to calculate Medicare Disproportionate Share Hospital (DSH) percentages
- to conduct quality review and improvement activities for Medicare coverage purposes
- to conduct evaluations and other analysis to support the Medicare program (including demonstrations)
- to support public health initiatives and other health care-related research
- for activities to support the administration of the Medicare program
- for activities conducted to support program integrity
- for purposes authorized by applicable law

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

Records may be disclosed to parties outside HHS, without the individual record subject's prior, written consent, for the following purposes:

1. To determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c), 423.329, and 460.180, to update risk adjustment models, to calculate Medicare DSH percentages, to conduct quality review and improvement activities, for Medicare coverage purposes, to conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives, for activities conducted to support program integrity, and for purposes authorized by applicable law.

2. To support CMS contractors, consultants, or grantees that have been contracted by the Agency when necessary to assist in accomplishment of a CMS function relating to the purposes for this system or a purpose listed in paragraph 1.

3. To support an individual or organization for research to support the Medicare program and public health initiatives, and otherwise related to health care, such as evaluation or epidemiological projects related to the prevention of disease or disability, the restoration or maintenance of health, or for understanding and improving payment projects.

4. To provide information to the U.S. Department of Justice (DOJ), a court, or an adjudicatory body when (a) the Agency or any component thereof, or (b) any employee of the Agency in his or her official capacity, or (c) any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee, or (d) the United State Government, is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court, or adjudicatory body is compatible with the purpose for which the agency collected the records.

5. To assist a CMS contractor (including, but not limited to Medicare Administrative Contractors, fiscal intermediaries, and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.

6. To assist another Federal agency or an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local governmental agency), that

administers or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

7. To assist Medicare Advantage organizations, Part D Sponsors and PACE organizations with improving the quality of required risk adjustment data obtained from the provider that furnished the item or service. CMS will be analyzing the data received and advising MA organizations, Part D Sponsors and PACE organizations of trends and data analysis results to help improve the accuracy and completeness of data received from the provider.

8. To assist appropriate Federal agencies and CMS contractors and consultants that have a need to know the information for the purpose of assisting CMS' efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, provided that the information disclosed is relevant and necessary for that assistance.

Note: CMS may disclose information from this system of records, without the individual record subject's consent, for any of the following purposes referenced directly in the Privacy Act: 5 U.S.C. 552a(b)(1), (3)–(8), and (12). CMS must also disclose information from this system of records, without the individual record subject's consent, for any of the following purposes referenced directly in the Privacy Act: 5 U.S.C. 552a(b)(2), and (b)(9)–(11).

ADDITIONAL PROVISIONS AFFECTING ROUTINE USE DISCLOSURES:

This system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, 65 FR 82462 (12–28–00), subparts A and E). Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of data that is not directly identifiable, except if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals could, because of the small size, use this information to deduce the identity of the beneficiary).

Note: Information collected or obtained under § 1860D–15 (*i.e.,* risk adjustment data used to pay Part D plan sponsors) will be used and disclosed only in accordance with the statutory limitations under § 1860D–15(f)(2).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEMSTORAGE:

Archived records will be stored on magnetic tapes. Data that is currently in use is stored in the RAPS database.

RETRIEVABILITY:

Records will be retrieved by National Provider Identifier (NPI), beneficiary provider name, or beneficiary Health Insurance Claim Number.

SAFEGUARDS:

Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational, and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems; and to prevent unauthorized access. Access to records in the RASS will be limited to CMS personnel and contractors through password security, encryption, firewalls, and secured operating system(s).

RETENTION AND DISPOSAL:

Records (*i.e.,* enrollee diagnosis data files created in RAPS, and Risk Adjustment Factor (RAF) files created in RAS) will be maintained for a period of up to 10 years after date of creation. Any such records that are needed longer, such as to resolve claims and audit exceptions or to prosecute fraud, will be retained until such matters are resolved. Enrollee claims records are currently subject to a document preservation order and will be preserved indefinitely pending further notice from the U.S. Department of Justice (DOJ).

SYSTEM MANAGER AND ADDRESS:

Director, Division of Encounter Data and Risk Adjustment Operations, Medicare Plan Payment Group, Center for Medicare, CMS, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

Individuals (*i.e.,* the beneficiary or provider) wishing to know if this system contains records about them should write to the system manager and include pertinent personally identifiable information (encrypted and properly transmitted) to be used for retrieval of their records (*i.e.,* NPI or Health Insurance Claim Number).

RECORD ACCESS PROCEDURE:

Individuals seeking access to records about them in this system should follow the same instructions indicated under ''Notification Procedure'' and reasonably specify the record content being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest the content of information about them in this system should follow the same instructions indicated under ''Notification Procedure.'' The request should: reasonably identify the record and specify the information being contested; state the corrective action sought; and provide the reasons for the correction, with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

RASS processes data extracted from RAPS and RAS IT systems to calculate the risk scores used to adjust payments to Medicare Advantage organizations, Part D plan sponsors and PACE plans. RAS receives the most current data for each Medicare Part C and Part D beneficiary from the following sources: RAPS, Common Medicare Environment (CME) also known as Medicare Beneficiary Database (MBD/CME), and National Medicare Utilization Database (NMUD). RAPS receives risk adjustment data from MA organizations and other entities defined above.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Celeste Dade-Vinson,

Health Insurance Specialist, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–20224 Filed 8–14–15; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0103]

Botanical Drug Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Botanical Drug Development.'' This guidance describes FDA's current thinking on appropriate development plans for botanical drugs to be submitted in new drug applications (NDAs) and specific recommendations on submitting investigational new drug applications (INDs) in support of future NDA submissions for botanical drugs. In addition, this guidance provides general information on the over-the-counter (OTC) drug monograph system for botanical drugs. Although this guidance does not intend to provide recommendations specific to botanical drugs to be marketed under biologics license applications (BLAs), many scientific principles described in this guidance may also apply to these products. This draft guidance revises the guidance for industry entitled ''Botanical Drug Products'' issued in June 2004.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 16, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sau L. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4144, Silver Spring, MD 20993–0002, 301–796–2905, *Sau.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Botanical Drug Development.'' This guidance describes the Center for Drug Evaluation and Research's current thinking on appropriate development plans for botanical drugs to be submitted in NDAs and specific recommendations on submitting INDs in support of future NDA submissions for botanical drugs. In addition, this guidance provides general information on the OTC drug monograph system for botanical drugs. Although this guidance does not intend to provide recommendations specific to botanical drugs to be marketed under BLAs, many scientific principles described in this guidance may also apply to these products.

This guidance specifically discusses several areas in which, due to the unique nature of botanical drugs, the Agency finds it appropriate to apply regulatory policies that differ from those applied to nonbotanical drugs, such as synthetic, semi-synthetic, or otherwise highly purified or chemically modified drugs, including antibiotics derived from microorganisms. Because this guidance focuses on considerations unique to botanical drugs, policies and recommendations applicable to both botanical and nonbotanical drugs are generally not covered in this document.

This guidance revises the final guidance for industry entitled ''Botanical Drug Products'' issued in June 2004. The general approach to botanical drug development has remained unchanged since that time; however, based on improved understanding of botanical drugs and experience acquired in the reviews of NDAs and INDs for these drugs, specific recommendations have been modified and new sections have been added to better address late-phase development and NDA submission for botanical drugs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on botanical drug development. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The guidance explains the circumstances under which FDA regulations require approval of an NDA for marketing a botanical drug product and when such a product may be marketed under an OTC drug monograph. The regulations governing the preparation and submission of an NDA are in part 314 (21 CFR part 314), and the guidance does not contain any recommendations that exceed the requirements of these regulations. FDA has estimated the information collection requirements resulting from the preparation and submission of an NDA, and OMB has approved the burden under OMB control number 0910–0001. FDA anticipates that any NDAs submitted for botanical drug products would be included under the burden estimates approved by OMB for part 314.

The regulations on the procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing OTC drug monographs, are set forth in § 330.10 (21 CFR 330.10). FDA believes that any botanical drug products that may be eligible for inclusion in an OTC drug monograph under current § 330.10 have already been or presently are being considered for such inclusion.

The guidance also provides scientific and regulatory guidance to sponsors on conducting clinical investigations of botanical drugs. The regulations governing the preparation and submission of INDs are in part 312 (21 CFR part 312). The guidance does not contain any recommendations that exceed the requirements in those regulations. FDA has estimated the information collection requirements resulting from the preparation and submission of an IND under part 312, and OMB has approved the reporting and recordkeeping burden under OMB control number 0910–0014.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20230 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0012]

Disease Natural History Database Development—(U24)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of Natural History Database Development. The National Organization for Rare Disorders (NORD) is developing an Internet-based data collection tool with promise to further the accumulation of natural history data for many rare diseases. The goal of this grant is to enable NORD to further develop, refine, and disseminate the database tool.

DATES: Important dates are as follows:

1. The application due date is September 4, 2015.
2. The anticipated start date is September 2015.
3. The opening date is July 2015.
4. The expiration date is September 5, 2015.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov.* For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: James Kaiser, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–1237, *james.kaiser@fda.hhs.gov.*

Vieda Hubbard, Office of Acquisition and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 240–402–7588, *Vieda.Hubbard@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *www.grants.gov.* Search by Funding Opportunity Number: RFA–FD–15–038.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–15–038
93.103

A. Background

There are an estimated 7,000 rare diseases, in total affecting approximately 30 million Americans. Most of these are serious conditions with no approved therapies. Rare diseases constitute an enormous unmet medical need.

Drug development for rare diseases, as well as for common diseases, relies on an indepth knowledge of the diseases' natural histories. Natural history is the course of the disease in the absence of a clinical intervention (that is, treatment under clinical care or study). Natural history knowledge makes possible the design of successful and efficient drug development programs. This knowledge has wide-ranging applications at every stage of drug development, for example, insight into the mechanism of disease, which can inform proof-of-concept studies; development of biomarkers that can expedite clinical studies at every stage of drug development; recognition and understanding of phenotypes of disease that may respond more (or less) to a therapy; and knowledge of the aspects of disease that matter to patients, with an impact on developing drugs that have a meaningful impact on how a patient feels, functions, or survives. The lack of natural history knowledge can result in the failure of drug programs, even for drugs with great promise. Unfortunately, the natural history of rare diseases is often poorly understood.

Impediments to the understanding of the natural history of a rare disease include the small numbers of patients and the sparse dispersal of clinical experience even among the chief clinical referral centers. The rare disease community is largely composed of small, diverse groups including patient and patient-family support, nonprofit disease groups (including umbrella groups), academic researchers, and small- to medium-sized biotechnology and pharmaceutical companies. For most rare diseases there has been no mechanism to systematically collect rare disease knowledge. In addition, it has become increasingly clear that it is vitally important to collect more knowledge from living patients over time, not simply to collect currently available information. This ''longitudinal'' information about individual patients is invaluable to the design of a drug development program. The rare disease community is in need of a means of collecting and analyzing this knowledge: A natural history database tool.

B. Research Objectives

The development of natural history databases will directly further FDA's public health mission. We anticipate that the successful implementation of a natural history database will have profound and far-reaching effects on development of therapies for rare diseases. As a basis for solid natural history knowledge of a disease it may help to make a clinical development program for a candidate therapy appear feasible, and thus a more attractive area to pharmaceutical companies for devoting a portion of their drug discovery resources. This too will lead to greater numbers of therapies for rare diseases.

C. Eligibility Information

Only the following organization is eligible to apply: The National Organization for Rare Disorders. NORD is uniquely qualified to apply for this grant as the only applicant. Natural history studies is an area of unmet need and there are very few efforts towards building these studies. Those efforts that exist are very limited to specific diseases (*e.g.,* cystic fibrosis, urea cycle disorders). These individual efforts cannot and do not support other patient groups starting their own studies. Most efforts are largely focused on patient communication and patient reports through Web-based self-reporting and are not likely to conform to sufficient scientific rigor to be able to support drug development. Although patient registries exist, these are not the same thing as natural history studies, and can often be very broad and general and cannot be customized to the depth and scope needed to support multiple natural history studies in a diverse group of rare diseases. The rigor, scope, and flexibility of NORD's platform, which comes from approximately 15 years of working with the rare disease community on these efforts, is unique and directly suited to the needs of FDA.

II. Award Information/Funds Available

A. Award Amount

FDA/Center for Drug Evaluation and Research intends to fund up to $250,000, for fiscal year 2015 in support of this grant program. It is anticipated that one award will be made, not to

exceed $250,000 in total costs (direct plus indirect).

B. Length of Support

The maximum project period is 1 year.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at *www.grants.gov.* Search by Funding Opportunity Number: RFA–FD–15–038. For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit electronic applications to *http://www.grants.gov.*

Dated: August 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20130 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2735]

Scientific Inquiry Into How Mobile Health and Social Data Sources May Inform Medical Product Safety and Efficacy; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland's Center of Excellence in Regulatory Science and Innovation (M–CERSI) is announcing a public workshop entitled ''Scientific Inquiry Into How Mobile Health and Social Data Sources May Inform Medical Product Safety and Efficacy.'' The purpose of the public workshop is to discuss important scientific questions about using two of the most ubiquitous and fastest growing data sources, mobile health data and social computing data, focusing especially on the implications for product safety.

DATES: The public workshop will be held on September 11, 2015, from 12:30 p.m. to 5:30 p.m.

ADDRESSES: The public workshop will be held at the Adele H. Stamp Student Union, University of Maryland, 1021A Adele H. Stamp Student Union, College Park, MD. For additional travel and hotel information, please refer to: *http://go.umd.edu/mobilesocialanalytics.*

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *Regarding this notice:* Leslie D. Wheelock, Food and Drug Administration, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 1, Rm. 4345, Silver Spring, MD 20993, 301–796–8450, FAX: 301–847–8106; email: *leslie.wheelock@fda.hhs.gov.*

Regarding registration: Ann Anonsen, University of Maryland, Fischell Dept. of Bioengineering, 2207 Jeong H. Kim Bldg., College Park, MD 20742, 301–405–0285, FAX: 301–405–9953, email: *aanonsen@umd.edu.*

SUPPLEMENTARY INFORMATION:

I. Background

Mobile health and social computing data sources create unique and hitherto unavailable opportunities, but there are important questions that need to be answered. This workshop will bring together thought leaders from industry, academia, and the regulatory communities to reflect on the opportunities and challenges that these new data sources create.

II. Attendance and Registration

There is a registration fee to attend this public workshop. The registration fee is charged to help defray the costs for facilities, materials, and food. Seats are limited, and registration will be on a first-come, first-served basis. The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	$50
Charitable Nonprofit/Academic	50
Government/Students	0

Persons interested in attending this public workshop must register online at *http://go.umd.edu/mobilesocialanalytics* by September 1, 2015. To register, please refer to: *http://www.rhsmith.umd.edu/centers-excellence/center-health-information-decision-systems/events/m-cersi-workshop.* Early registration is recommended because space is limited. Those without Internet access should contact Ann Anonsen to register (see **FOR FURTHER INFORMATION CONTACT** regarding registration).

Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Ann Anonsen, at 301–405–0285 or email: *aanonsen@umd.edu.*

III. Comments

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). The deadline for submitting comments related to this public workshop is August 28, 2015. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: August 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20129 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0332]

Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices.'' National outbreaks of Toxic Anterior Segment Syndrome (TASS) have been associated with single-use intraocular ophthalmic devices (IODs) and single-use intraocular ophthalmic surgical instruments/accessories that are contaminated with endotoxins. These devices can become contaminated as part of the manufacturing, sterilization, or packaging processes. This guidance document provides recommendations for endotoxin limits as well as endotoxin testing to manufacturers and other entities involved in submitting premarket applications (PMAs) or premarket notification submissions (510(k)s) for different categories of IODs to mitigate future outbreaks of TASS.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2504, Silver Spring, MD 20993–0002, 301–796–5620.

SUPPLEMENTARY INFORMATION:

I. Background

TASS has been increasing in frequency over the past decade from approximately 1 in 1,000 to about 2 in 100. Some cases of TASS are severe enough to require secondary surgical interventions including glaucoma surgery and corneal transplantation. The use of inadequately or improperly processed ophthalmic surgical instruments is one of many factors suggested as a potential cause of TASS. In many TASS cases, bacterial endotoxin from medical devices is believed to cause the inflammation.

This guidance document was developed to notify manufacturers and other entities involved in submitting PMAs or 510(k)s for different categories of IODs of the recommended endotoxin limit for the release of IODs and single-use intraocular ophthalmic surgical instruments/accessories in an effort to mitigate future TASS outbreaks.

The draft of this guidance was made available in the **Federal Register** on April 17, 2014 (79 FR 21777), and the comment period closed July 16, 2014. Only two sets of comments were received. The comments were minor, and FDA made revisions to the document in response to the comments where appropriate. FDA also removed posterior segment devices from the scope of the guidance document. FDA may address endotoxin testing recommendations for this device type in future guidance documents.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on endotoxin testing and limits for single-use IODs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1836 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20229 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2843]

Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease.'' This draft guidance provides a qualified context of use (COU) for total kidney volume (TKV), measured at baseline, to be used as a prognostic enrichment biomarker to select patients with autosomal dominant polycystic kidney disease (ADPKD) at high risk for a ''progressive decline'' in renal function, defined as a confirmed 30 percent decline in the patient's estimated glomerular filtration rate (eGFR), for inclusion in interventional clinical trials. This draft guidance also describes the experimental conditions and constraints for which this biomarker is qualified through the Center for Drug Evaluation and Research (CDER) Biomarker Qualification Program. This biomarker can be used by drug developers for the qualified COU in submissions of investigational new drug applications, new drug applications, and biologics license applications without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker.

In the **Federal Register** of January 7, 2014, FDA announced the availability of a final guidance for industry entitled ''Qualification Process for Drug Development Tools'' that described the process that would be used to qualify Drug Development Tools (DDTs) and to make new DDT qualification recommendations available on FDA's Web site. The qualification recommendations in this draft guidance were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 16, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marianne Noone, Center for Drug Evaluation and Research (Office of Translational Sciences, Immediate Office), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4528, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease.'' This draft guidance provides qualification recommendations for the use of TKV, measured at baseline, as a prognostic enrichment biomarker to select patients with ADPKD at high risk for a ''progressive decline'' in renal function, defined as a confirmed 30 percent decline in the patient's eGFR, for inclusion in interventional clinical trials. This biomarker may be used in combination with the patient's age and baseline eGFR as an enrichment factor in these interventional clinical trials. Specifically, this draft guidance provides the COU for which this biomarker is qualified through the CDER Biomarker Qualification Program. Qualification of this biomarker for this specific COU represents the conclusion that analytically valid measurements of the biomarker can be relied on to have a specific use and interpretable meaning. This biomarker can be used by drug developers for the qualified COU in submission of investigational new drug applications, new drug applications, and biologics license applications without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker. ''Qualification'' means that the use of this biomarker in the specific COU is not limited to a single, specific drug development program. Making the qualification recommendations widely known and available for use by drug developers will contribute to drug innovation, thus supporting public health.

In the **Federal Register** of January 7, 2014 (79 FR 831), FDA announced the availability of a final guidance for industry entitled ''Qualification Process for Drug Development Tools'' that described the process that would be used to qualify DDTs and to make new DDT qualification recommendations available on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*. The current draft guidance is an attachment to that final guidance.

CDER has initiated this formal qualification process to work with developers of these biomarker DDTs to guide them as they refine and evaluate DDTs for use in the regulatory context. Once qualified, biomarker DDTs will be publicly available for use in any drug development program for the qualified COU. As described in the January 2014 guidance, biomarker DDTs should be developed and reviewed using this process. For more information on FDA's DDTs Qualification Programs, refer to the following Web page: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm*.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the use of TKV, measured at baseline, as a prognostic enrichment biomarker to select patients with ADPKD at high risk for a progressive decline in renal function, defined as a confirmed 30 percent decline in eGFR, for inclusion in interventional clinical trials. This biomarker may be used in combination with patient age and baseline eGFR, as an enrichment factor in these interventional clinical trials. It does not establish any rights for any person and not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains an information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information collection has been approved under the OMB control numbers 0910–0001 and 0910–0014. The information requested in this guidance is currently submitted to FDA to support medical product effectiveness (see 21 CFR 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6)).

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20228 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2818]

Rare Diseases: Common Issues in Drug Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Rare Diseases: Common Issues in Drug Development.'' The purpose of this draft guidance is to advance and facilitate the development of drugs and biologics to treat rare diseases. Drug development for rare diseases has many challenges related to the nature of these diseases. This draft guidance is intended to assist sponsors of drug and biological products for treating rare diseases in conducting more efficient and successful development programs.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 16, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonathan Goldsmith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6480, Silver Spring, MD 20903–0002, 240–402–9959; or Stephen Ripley, 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:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Rare Diseases: Common Issues in Drug Development.'' This guidance is intended to assist sponsors of drug and biological products for treating rare diseases in conducting more efficient and successful development programs through a discussion of selected issues commonly encountered in rare disease drug development. Although these issues are encountered in other drug development programs, they are frequently more difficult to address in the context of a rare disease than a common disease for which there is greater and more widespread medical experience. These issues are also more acute with increasing rarity of the disorder. A rare disease is defined by the Orphan Drug Act as a disorder or condition that affects less than 200,000 persons in the United States; however, most rare diseases affect far fewer persons.

Most rare disorders are serious conditions with no approved treatments, and rare disease patients have considerable unmet medical needs. Collectively, rare diseases are highly diverse. FDA is committed to helping sponsors of drugs for rare diseases create successful programs that address the particular challenges posed by each disease.

This guidance addresses the following important components of drug development:

- Adequate description and understanding of the disease's natural history
- Adequate understanding of the pathophysiology of the disease and the drug's proposed mechanism of action
- Nonclinical pharmacotoxicology considerations to support the proposed clinical investigation(s)
- Standard of evidence to establish safety and effectiveness
- Drug manufacturing considerations during drug development

Early consideration of these issues allows sponsors to efficiently and adequately address them during the course of drug development, from drug discovery to confirmatory efficacy and safety studies, and to have productive meetings with FDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on common issues in drug development for rare diseases. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20235 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1176]

Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the document that appeared in the **Federal Register** of May 19, 2015. In the document, FDA requested comments on draft guidance for industry (GFI) #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' FDA is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published May 19, 2015 (80 FR 28624). Submit either electronic or written comments on the draft guidance by November 16, 2015.

ADDRESSES: You may submit comments by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written comments in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2015–D–1176. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Division of Compliance, Center for Veterinary Medicine, Food and Drug Administration (HFV–230), 7519 Standish Pl., Rockville, MD 20855, 240–402–7001, *CVMCompliance@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 19, 2015, FDA published a document with a 90-day comment period for draft GFI #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' The draft guidance describes FDA's policies with regard to compounding animal drugs from bulk drug substances. When final, the guidance will reflect FDA's current thinking on the issues addressed by the guidance.

FDA has received a request for a 90-day extension of the comment period. The request conveyed concern that the current 90-day comment period does not allow sufficient time to respond. FDA has considered the request and is extending the comment period for 90 days, until November 16, 2015. FDA believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this guidance document.

II. Specific Topics for Comment

In addition to comments on the draft guidance as written, we are specifically requesting comments on the following issues:

- Should the final guidance address the issue of FDA-approved animal and human drugs that are in shortage or are otherwise unavailable (*e.g.,* disruptions in the manufacture or supply chain; business decisions to stop marketing the drug; drug is subject to Agency action based on safety, effectiveness, or manufacturing concerns)? If so:
  - How should these situations be addressed in the final guidance?
  - How should the final guidance define the terms ''shortage'' and ''unavailable''?
  - What criteria should FDA use to determine if an approved animal or human drug is in shortage or otherwise unavailable?
- Do United States Pharmacopeia and National Formulary (USP–NF) [1] chapters 795 and 797 provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians?
- Should licensed veterinarians be able to sell or transfer an animal drug compounded from bulk drug substances by a State-licensed pharmacy or an outsourcing facility to owners or caretakers of animals under the veterinarian's care?
- Should the final guidance include a condition on the amount or percentage of compounded animal drugs that a pharmacy or outsourcing facility can ship in interstate commerce? If so, what would a reasonable amount be?
- Is additional guidance needed to address the repackaging of drugs for animal use?
  - How widespread is the practice of repackaging drugs for animal use?
  - What types of drugs are repackaged for animal use, and why are they repackaged?
  - Have problems been identified with repackaged drugs for animal use?
- Is additional guidance needed to address the compounding of animal drugs from approved animal or human drugs under section 512(a)(4) or (a)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(a)(4) and (a)(5)) and 21 CFR part 530?
- Is additional guidance needed to address the compounding of animal drugs from bulk drug substances for food-producing animals?

[1] Chapters <795> ''Pharmaceutical Compounding—Nonsterile Preparations'' and <797> ''Pharmaceutical Compounding—Sterile Preparations'' can be found in both the *USP Compounding Compendium* and the combined *United States Pharmacopeia and National Formulary (USP–NF).* These compendia are available at *http://www.usp.org/*.

• As one condition under which FDA does not generally intend to take action for certain violations of the FD&C Act if this and the other conditions are followed, FDA is proposing that State-licensed pharmacies and veterinarians report any product defect or serious adverse event associated with animal drugs they compound from bulk drug substances to FDA within 15 days of becoming aware of the product defect or serious adverse event. Outsourcing facilities are required to report adverse events associated with the drugs they compound. FDA believes it is important to receive this information from State-licensed pharmacies and veterinarians because there are no other State Departments of Health or Federal Agencies (*e.g.,* the Centers for Disease Control and Prevention) charged with identifying and tracing animal injuries or disease associated with an animal drug compounded by these entities. FDA has the following specific questions with respect to this proposed condition:

○ How many State-licensed pharmacies and veterinarians compound animal drugs from bulk drug substances and would potentially be reporting product defects and serious adverse events to FDA?

○ Are State-licensed pharmacies and veterinarians reporting the same or similar information to any State regulatory agency (*e.g.,* State boards of pharmacy, State boards of veterinary medicine)? If so, how many reports on average does each State-licensed pharmacy and veterinarian submit to these State agencies each year?

○ For purposes of the guidance, how should FDA define the terms ''product defect'' and ''serious adverse event?''

○ Can FDA achieve the same objective of identifying and tracing the source of injuries or disease associated with an animal drug compounded from a bulk drug substance through means other than product defect and serious adverse event reporting, and if so, what other means? For example, would reports of product defects alone achieve the same objective?

III. Request for Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm* or *http://www.regulations.gov.*

Dated: August 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20174 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2734]

Physiological Closed-Loop Controlled Devices; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Physiological Closed-Loop Controlled (PCLC) Devices.'' The topic to be discussed is challenges related to the design, development, and evaluation of critical care PCLC devices. FDA considers PCLC devices an emerging technology and aims to hold a workshop focusing on design, development and performance evaluation of PCLC systems intended for use in critical care environments. Such devices include closed-loop anesthetic delivery, closed-loop vasoactive drug and fluid delivery, and closed-loop mechanical ventilation.

Dates and Times: The public workshop will be held on October 13 and 14, 2015, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Rm. 1503 (The Great Room), Silver Spring, MD 20993.

Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Persons: Bahram Parvinian, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2534, Silver Spring, MD 20993, 301–796–6445, email: *Bahram.Parvinian@fda.hhs.gov;* and Allison Kumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5402, Silver Spring, MD 20993, 301–796–6369, email: *Allison.Kumar@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m., October 1, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Office of Communication and Education (OCE), Center for Devices and Radiological Health, Food and Drug Administration, 301–796–5661, email: *susan.monahan@fda.hhs.gov* no later than September 29, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 4 p.m., October 1, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 7, 2015. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has

verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This public workshop includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 15, 2015. All requests to make oral presentations must be received by September 1, 2015. If selected for presentation, any presentation materials must be emailed to Bahram Parvinian and Allison Kumar (see *Contact Persons*) no later than October 1, 2015. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain information on challenges related to the design, development, and evaluation of critical care PCLC devices. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is September 1, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The address of the Division of Freedom of Information is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

PCLC medical devices are an emerging technology in the intensive care and emergency medicine settings that provides autonomous therapy adjustments to manipulate a physiological variable. For example, a closed-loop oxygen delivery device may automatically adjust the fraction of inspired oxygen when an individual's oxygen saturation level drifts too high or too low. PCLCs could benefit patients and practitioners by automating a number of tasks including adjustments to mechanical ventilation, anesthetic delivery, and fluid resuscitation. These devices may provide practitioners more resources to consider the course of treatment for an individual patient and improve resource allocation during times of medical surge (*e.g.*, from mass casualty incidents). PCLC medical devices may also allow additional therapeutic and diagnostic capabilities by providing precise control of physiological variables by continuous manipulation of therapy that is impractical for a medical practitioner to perform.

Recent advances in medical device technology and control systems science have increased the development of PCLC medical devices. PCLCs shift specific assignments of data interpretation and therapy manipulation from a practitioner to a medical device. This may or may not introduce new risks to patients, but could introduce new medical device hazards that, considered during design and development, can be mitigated throughout the device life-cycle. Addressing technical and clinical challenges for a PCLC medical device to be robust, stable, and effective in its environment of use will ensure patient safety and promote innovation and development of PCLC medical devices.

This workshop seeks to involve industry, academia, medical societies, patient groups, standard bodies, and other relevant stakeholders in addressing the challenges in the development and implementation of PCLC medical devices in critical care environments. Participants in the workshop will include scientists and engineers developing PCLC medical devices, as well as end users including physicians, nurses, and patients. The intent of the workshop is to discuss benefit-risk considerations, design strategies, pre-clinical testing, and clinical evaluation for specific product areas of PCLC medical devices. Ideas generated during this workshop may facilitate development of new draft guidances and/or standards for PCLC medical devices.

II. Topics for Discussion at the Public Workshop

This workshop is aimed to address the scientific, clinical and regulatory considerations associated with these devices, including, but not limited to, the following topic areas:

1. Benefit-risk considerations at varying levels of closed-loop medical device autonomy

2. Challenges related to the design and development of critical care PCLC devices

a. System performance analysis for different controller types (*e.g.,* rule based/knowledge based, proportional-integral derivative, fuzz logic, adaptive predictive, neural networks)

b. Fault detection and fallback modes

c. User interfaces and operational transparency

3. Knowledge gap between clinicians and system engineers

a. Clinician involvement in system design

b. Control system terminology

4. Pre-clinical evaluation

a. Evidence needed to demonstrate a stable and robust controller

b. Use of computer simulations including verification, validation and uncertainty quantification of physiological models used for design and evaluation of PCLC systems.

c. Real time bench testing

5. Clinical evaluation (*e.g.,* study design, clinical endpoints, outside the U.S. data)

a. Clinical validity of sensors

b. Patient populations

c. Environments of use

d. User related level of expertise.

6. Human factors of autonomous medical devices (*e.g.,* usability, training, clinical decisionmaking)

Dated: August 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20127 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than October 16, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: National Health Service Corps Scholar/Students to Service Travel Worksheet.

OMB No. 0915–0278—Extension.

Abstract: Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program and the Students to Service (S2S) Loan Repayment Program use the online Travel Request Worksheet to receive travel funds from the federal government to visit eligible NHSC sites to which they may be assigned in accordance with the Public Health Service Act (PHSA), section 331(c)(1).

The travel approval process is initiated when a NHSC scholar or S2S participant notifies the NHSC of an impending interview at one or more NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after an NHSC scholar or S2S participant has successfully been matched to an approved practice site in accordance with the PHSA, section 331(c)(3). Upon receipt of the Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the scholar or S2S participant, and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

Need and Proposed Use of the Information: This information will facilitate NHSC scholar and S2S clinicians' receipt of federal travel funds that are used to visit high-need NHSC sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar or S2S participant has successfully been matched to an approved practice site. This information will be used by the NHSC in order to make travel arrangements for NHSC scholar and S2S clinicians to potential practice sites and to assist them in relocation arrangements once clinicians have secured employment at one of these sites.

Likely Respondents: Clinicians participating in the National Health Service Corps Scholarship Program and the Students to Service Loan Repayment 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 Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Travel Request Worksheet	250	2	500	.0667	33
Total	250	2	500	.0667	33

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–20135 Filed 8–14–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30)

provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities'' unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 9¾%, as fixed by the Secretary of the Treasury, is certified for the quarter ended June 30, 2015. This rate is based on the Interest Rates for Specific Legislation, ''National Health Services Corps Scholarship Program (42 U.S.C. 250(B)(1)(A))'' and ''National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).'' This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

Dated: August 7, 2015.

Teresa V. Miranda,

Director, Division of Financial Management Policy.

[FR Doc. 2015–20217 Filed 8–14–15; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, with a short public comment period at the end. Attendance is limited by the 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 open session will also be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov/*).

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 General Medical Sciences Council.

Date: September 17–18, 2015.

Closed: September 17, 2015, 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Open: September 18, 2015, 8:30 a.m. to Adjournment.

Agenda: For the discussion of program policies and issues, opening remarks, report of the Director, NIGMS, and other business of the Council.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Ann A. Hagan, Ph.D., Associate Director for Extramural Activities, NIGMS, NIH, DHHS, 45 Center Drive, Room 2AN24H, MSC 6200, Bethesda, MD 20892, (301) 594–4499, *hagana@nigms.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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Information is also available on the Institute's home page (*http://www.nigms.nih.gov/About/Council/*) where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 12, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–20210 Filed 8–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Center for Scientific Review Advisory Council.

The meeting will be open to the public, 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.

Name of Committee: Center for Scientific Review Advisory Council.

Date: September 28, 2015.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: Provide advice to the Director, Center for Scientific Review (CSR), on matters related to planning, execution, conduct, support, review, evaluation, and receipt and referral of grant applications at CSR.

Place: Bethesda Marriott, Congressional Ballroom, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Rene Etcheberrigaray, M.D., Deputy Director, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3030, MSC 7776, Bethesda, MD 20892, (301) 435–1111, *etcheber@csr.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://public.csr.nih.gov/aboutcsr/CSROrganization/Pages/CSRAC.aspx*, where an agenda and any additional information for the meeting will be posted when available.

(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: August 12, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–20212 Filed 8–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: September 10, 2015.

Time: 12:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Room 3F100, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Louis A. Rosenthal, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Rm 3G42B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC–79823, Bethesda, MD 20892–9823, (240) 669–5070, *rosenthalla@niaid.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: August 12, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–20211 Filed 8–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Kidney Interagency Coordinating Committee Meeting

SUMMARY: The Kidney Interagency Coordinating Committee (KICC) will hold a meeting on September 25, 2015, on the pharmacist's role in chronic kidney disease care. The meeting is open to the public.

DATES: The meeting will be held on September 25, 2015, 9 a.m. to 12 p.m. Individuals wanting to present oral comments must notify the contact person at least 10 days before the meeting date.

ADDRESSES: The meeting will be held in the Natcher Conference Center on the NIH Campus at 9000 Rockville Pike, Bethesda, MD 20894.

FOR FURTHER INFORMATION CONTACT: For further information concerning this meeting, contact Dr. Andrew S. Narva, Executive Secretary of the Kidney Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 31 Center Drive, Building 31A, Room 9A27, MSC 2560, Bethesda, MD 20892–2560, telephone: 301–594–8864; FAX: 301–480–0243; email: *nkdep@info.niddk.nih.gov*.

SUPPLEMENTARY INFORMATION: The KICC, chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), comprises members of the Department of Health and Human Services and other federal agencies that support kidney-related activities, facilitates cooperation, communication, and collaboration on kidney disease among government entities. KICC meetings, held twice a year, provide an opportunity for Committee members to learn about and discuss current and future kidney programs in KICC member organizations and to identify opportunities for collaboration. The September 25, 2015 KICC meeting will focus on the pharmacist's role in chronic kidney disease care.

Any member of the public interested in presenting oral comments to the Committee should notify the contact person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives or organizations should submit a letter of intent, a brief description of the organization represented, and a written copy of their oral presentation in advance of the meeting. Only one representative of an organization will be allowed to present; oral comments and presentations will be limited to a maximum of 5 minutes. Printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committee by forwarding their 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. Because of time constraints for the meeting, oral comments will be allowed on a first-come, first-serve basis.

Members of the public who would like to receive email notification about future KICC meetings should send a request to *nkdep@info.niddk.nih.gov*.

Dated: August 4, 2015.

Camille M. Hoover,

Executive Officer, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

[FR Doc. 2015–20219 Filed 8–14–15; 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 (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel, Predoctoral Training Programs in Big Data Science.

Date: September 24, 2015.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Feng Tao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 6184, MSC 7849, Bethesda, MD 20892, (301) 451–3940, *feng.tao@nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Neurotransporters, Receptors, and Calcium Signaling Study Section.

Date: September 28–29, 2015.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco, 700 F Street NW., Washington, DC 20001.

Contact Person: Peter B Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4182, MSC 7850, Bethesda, MD 20892, (301) 435–1239, *guthriep@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Shared Instrumentation: Genomics.

Date: September 30, 2015.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Richard Panniers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@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: August 12, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–20213 Filed 8–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: September 10, 2015.

Open: 8:30 a.m. to 2:30 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's Report, NIH Health Disparities update, and other business of the Council.

Place: National Institutes of Health, National Institute on Minority Health and Health Disparities, 31 Center Drive, Building 31, Conference Room 6, Bethesda, MD 20892.

Closed: 2:30 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Minority Health and Health Disparities, 31 Center Drive, Building 31, Conference Room 6, Bethesda, MD 20892.

Contact Person: Dr. Joyce Hunter, Executive Secretary, National Institutes of Health, National Institute on Minority Health and Heath Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 402–1366, *hunterj@nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit).

Dated: August 12, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–20220 Filed 8–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of Freeboard International as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Freeboard International as a commercial gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Freeboard International has been approved to gauge petroleum and certain petroleum products for customs purposes for the next three years as of April 1, 2015.

DATES: *Effective Dates:* The approval of Freeboard International as commercial gauger became effective on April 1, 2015. The next triennial inspection date will be scheduled for April 2018.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.13, that Freeboard International, 2500 Brunswick Ave., Linden, NJ 07036, has been approved to gauge petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.13. Freeboard International is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API Chapters	Title
1	Vocabulary.
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the

U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*

Dated: August 5, 2015.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2015–20153 Filed 8–14–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Saybolt LP has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of April 15, 2015.

DATES: *Effective Dates:* The accreditation and approval of Saybolt LP as commercial gauger and laboratory became effective on April 15, 2015. The next triennial inspection date will be scheduled for April 2018.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Saybolt LP, 21730 S. Wilmington Ave., Suite 201, Carson, CA 90810, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Saybolt LP is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API Chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
17	Maritime measurement.

Saybolt LP is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–07	D4807	Standard Test Method for Sediment in Crude Oil by Membrane Filtration.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–46	D5002	Density of Crude Oils by Digital Density Meter.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*.

Dated: August 5, 2015.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2015–20149 Filed 8–14–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of AmSpec Services, LLC, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec Services, LLC, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec Services, LLC, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of April 30, 2015.

DATES: *Effective Dates:* The accreditation and approval of AmSpec Services, LLC, as commercial gauger and laboratory became effective on April 30, 2015. The next triennial inspection date will be scheduled for April 2018.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite

1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec Services, LLC, 4370 Oakes Rd., Unit 732, Davie FL 33314, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. AmSpec Services, LLC is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API Chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
9	Density Determinations.
12	Calculations.
17	Maritime Measurement.

AmSpec Services, LLC is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–02	D1298	Standard Practice for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Meter.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–20	D4057	Standard Practice for Manual Sampling of Petroleum and Petroleum Products.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method.
27–57	D7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: August 6, 2015.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2015–20148 Filed 8–14–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2013–0015]

RIN 1660–AA79

Notice of Adjustment of Legitimate Amount in Dispute for the Dispute Resolution Pilot Program for Public Assistance Appeals

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: FEMA gives notice of an increase of the legitimate amount in dispute for the Dispute Resolution Pilot Program for Public Assistance Appeals for disasters declared on or after October 30, 2012.

DATES: *Effective Date:* August 17, 2015.

FOR FURTHER INFORMATION CONTACT: William Roche, Public Assistance Division Director, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472–3100, Phone: (202) 646–3834 or Email: *william.roche@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Sandy Recovery Improvement Act of 2013, Public Law 113–2, 127 Stat. 43 (Jan. 29, 2013), 42 U.S.C. 5189a note, prescribes that the Administrator shall annually adjust the legitimate amount in dispute under the Dispute Resolution Pilot Program to reflect changes in the Consumer Price Index for all Urban Consumers published by the Department of Labor. See 44 CFR 206.210(c)(1).

FEMA gives notice of an increase in the legitimate amount in dispute under the Dispute Resolution Pilot Program for Public Assistance Appeals to $1,031,000 for all disasters declared on or after October 30, 2012.

FEMA bases the adjustment on an increase in the Consumer Price Index for All Urban Consumers provided by The Bureau of Labor Statistics of the U.S. Department of Labor. The sum of the annual average percent change from the two previous years (2013 and 2014) used in the adjustment is 3.1 percent.

Dated: June 15, 2015.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2015–17068 Filed 8–14–15; 8:45 am]

BILLING CODE 9111–123–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2015–0047]

Privacy Act of 1974; Department of Homeland Security, U.S. Customs and Border Protection, DHS/CBP–001, Import Information System, System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to consolidate, update, and rename two current Department of Homeland Security systems of records titled, ''Department of Homeland Security/U.S. Customs and Border Protection, DHS/CBP–001 Automated Commercial Environment/International Trade Data System System of Records'' (7 FR 3109, January 19, 2006) and ''Department of Homeland Security/U.S. Customs and Border Protection, DHS/CBP–015 Automated Commercial System System of Records'' (73 FR 77759, December 19, 2008) as one new system of records. The consolidated system of records notice will be titled, ''Department of Homeland Security/U.S. Customs and Border Protection, DHS/CBP–001 Import Information System System of Records.'' This system of records will continue to collect and maintain records on all commercial goods imported into the United States, as well as information pertaining to the carrier, broker, importer, and other persons associated with the manifest, import, or commercial entry transactions for the goods.

As a result of a review of these two systems, the Department of Homeland Security/U.S. Customs and Border Protection is combining the system of records notices for these systems into one updated system of records notice that includes changes to the categories of individuals and to the categories of records regarding information maintained about persons who have account access to trade data in the system. The Department of Homeland Security/U.S. Customs and Border Protection is also including an additional routine use for disclosing vessel manifest information as required by statute, in addition to the new compilation of routine uses reconciled from the prior systems of records notices. Data from this system of records may be shared with law enforcement and/or intelligence agencies pursuant to the routine uses identified below. Additionally, the Department of Homeland Security is issuing a Notice of Proposed Rulemaking to exempt this system of records from certain provisions of the Privacy Act elsewhere in the **Federal Register**. Lastly, this notice includes non-substantive changes to simplify the formatting and text of the previously published notices. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before September 16, 2015. This updated system will be effective September 16, 2015.

ADDRESSES: You may submit comments, identified by docket number DHS–2015–0047 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 343–4010.
- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: John Connors (202) 344–1610, CBP Privacy Officer, Office of the Commissioner, U.S. Customs and Border Protection, Washington, DC 20229. For privacy questions, please contact: Karen L. Neuman, (202) 343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS), U.S. Customs and Border Protection (CBP) proposes to consolidate, update, and rename as one system of records notice (SORN) the information currently contained in two DHS SORNs titled, ''DHS/CBP–001 Automated Commercial Environment/International Trade Data System (ACE/ITDS) System of Records'' (7 FR 3109, January 19, 2006) and ''DHS/CBP–015 Automated Commercial System (ACS) System of Records'' (73 FR 77759, December 19, 2008) . This new SORN, entitled ''DHS/CBP–001 Import Information System (IIS),'' will inform the public about changes to the categories of individuals, categories of records, and routine uses contained in the consolidation of the former ACS and ACE/ITDS SORNs.

ACS, a decades old trade information database and information technology (IT) system, was deployed to track, control, and process all commercial goods imported into the United States. ACE, part of a multi-year modernization effort since 2001 to replace ACS, continues to be designed to manage CBP's import trade data and related transaction information. ACE/ITDS serves three sets of core stakeholders: The internal DHS/CBP users, Partner Government Agencies (PGA), and the trade community. ACE is the IT backbone for the ITDS, an interagency initiative formalized under the SAFE Port Act of 2006 to create a single window for the trade community and PGAs involved in importing and exporting. DHS/CBP has provided notice to the public and trade community that in the future, the ACS IT system will be fully phased out and replaced by ACE. As such, and to simplify the trade community's and the public's understanding of how trade information will be handled after ACE implementation, DHS/CBP is publishing this Import Information System (IIS) SORN to identify a single repository for import trade information. DHS/CBP is also publishing an updated ACE Privacy Impact Assessment on its Web site (*http://www.dhs.gov/privacy*) to inform the public of the operation and interconnectedness of the IT systems, ACS and ACE, and to assess the privacy impact of these systems using the fair information practice principles. This IIS system of records allows DHS/CBP to collect and maintain records on all commercial goods imported into the United States, along with related information about persons associated with those transactions, and manifest information.

As part of this consolidation and issuance of IIS, the category of individuals and category of records sections in the former ACS and ACE–ITDS have been merged to account for the data in both IT systems, as well as paper records related to the information in these systems. The category of individuals section is amended to remove reference to DHS/CBP employees and employees of other federal agencies for purposes of maintaining their user access accounts to the ACE–ITDS Portal, because these

individuals are now covered under a DHS-wide SORN, ''DHS/ALL–004 General Information Technology Access Account Records System (GITAARS) (77 FR 70792, November 27, 2012). The category of records for IIS will also include notations and results of examinations and document review for cleared merchandise to clarify and better identify DHS and PGA-generated information related to the processing of the import entry transaction. Additionally, the category of records is being expanded to address the expansion of information DHS/CBP proposes to collect on its revised Importer ID Input Record (CBP Form 5106). DHS/CBP is adding required elements for the name (First, Middle, Last) and business contact information (job title and phone) of Senior Company Officers of the Importer; DHS/CBP is also adding optional data fields on the form for the Senior Officers to provide Social Security number (SSN) or Passport Number and Country of Issuance. These latter, optional data elements are to facilitate Importer screening and verification.

The authorities sections from the previous SORNs have been combined, reconciled to address duplication, and updated to account for expanded information collected about business associations as part of the ACE–ITDS Portal user account. The purpose section for IIS reflects an update to the combined purposes for ACS and ACE–ITDS and addresses DHS/CBP's broad use of its import trade transaction IT systems (ACS and ACE) to collect and manage records to track, control, and process all commercial goods imported into the United States.

Consistent with DHS's information-sharing mission, information stored in the DHS/CBP–001 Import Information System (IIS) may be shared with other DHS Components that have a need to know the information to carry out their national security, law enforcement, immigration, or other homeland security functions. In addition, information may be shared with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this SORN and as otherwise authorized under the Privacy Act.

Information in IIS may be shared for the same routine uses as were previously published in ACS and ACE–ITDS, and are now updated in this document:

- ACS's former Routine Use K is now reclassified as Routine Use G.
  - Routine Use G permits sharing of data under the following circumstances: ''To appropriate federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, license, or treaty when DHS determines that the information would assist in the enforcement of civil or criminal laws.''
- ACE–ITDS's former Routine Use 3 is now reclassified as Routine Use K.
  - Routine Use K permits sharing of data under the following circumstances: ''To a federal, state, local, tribal, territorial, foreign, or international agency, maintaining civil, criminal, or other relevant enforcement information or other pertinent information, which has requested information relevant to or necessary to the requesting agency's or the bureau's hiring or retention of an individual, or issuance of a security clearance, license, contract, grant, or other benefit.''

Additionally, DHS/CBP is adding another routine use to IIS, Routine Use R, to provide explicit coverage for the mandated release of Manifest Information as set forth in section 1431 of title 19, United States Code and implemented through title 19, Code of Federal Regulations, part 103:

- Routine Use R permits sharing of data under the following circumstances: ''To paid subscribers, in accordance with applicable regulations, for the purpose of providing access to manifest information as set forth in 19 U.S.C. 1431.''

DHS/CBP will not assert any exemptions with regard to information provided by or on behalf of an individual. However, this data may be shared with law enforcement and/or intelligence agencies pursuant to the routine uses identified in the IIS SORN and as otherwise authorized under the Privacy Act. The Privacy Act requires that DHS maintain an accounting of such disclosures. Disclosing the fact that a law enforcement and/or intelligence agency has sought particular records may interfere with or disclose techniques and procedures related to ongoing law enforcement investigations. As such, DHS is issuing a Notice of Proposed Rulemaking to exempt this system of records from certain provisions of the Privacy Act elsewhere in the **Federal Register**. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all persons when systems of records maintain information on U.S. citizens, lawful permanent residents, and non-immigrant aliens.

Below is the description of the DHS/CBP–001 Import Information System (IIS) System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of these systems of records to the Office of Management and Budget and to Congress.

System of Records

Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP)–001.

SYSTEM NAME:

DHS/CBP–001 Import Information System (IIS).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained at the DHS/CBP Headquarters in Washington, DC and field offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals in this system include members of the public involved in the importation of merchandise and international trade, such as importers, brokers, carriers, manufacturers, shippers, consignees, cartmen/lightermen, filers, sureties, facility operators, foreign trade zone operators, drivers/crew, attorneys/consultants, and agents, in addition to persons required to file Customs Declarations for international mail transactions (including sender and recipient).

CATEGORIES OF RECORDS IN THE SYSTEM:

Information maintained by ACE as part of the *user account creation process* includes:

- *Account Information*—Including Name of Company, Name of Company Officer, Title of Company Officer, Company Organization Structure, and

Officer's Date of Birth (optional). For Operators, this information must match the name on the company's bond.

○ *Account Owner Information*—Name, Application Data, Email, Date of Birth, Country, Address, and Business Phone Number.

○ *Legal Entity Information*—Name, Application Data, Email, Country, Address, and Business Phone Number.

○ *Point of Contact Information*—Name, Application Data, Email, Country, Date of Birth, Address, and Business Phone Number.

• *Business Activity Information*—Depending on the account type being established, CBP requires the following identifying information to set up an ACE portal account. Users are limited to a single identification number for the portal account being requested with the exception of: Importer, broker, filer, software vendor, service bureau, port authority, preparer, or surety agent, which can use up to three identifying numbers for each portal view:

○ *Importer/Broker/Filer/Surety:* Importer Record Number; Filer Code; Taxpayer Identification Number (TIN) [*e.g.,* Internal Revenue Service (IRS) Employer Identification Number (EIN)/SSN]; Surety Code.

○ *Service Provider:* Standard Carrier Alpha Code (SCAC) or Filer Code; EIN/SSN.

○ *Operator:* EIN/SSN; Bond Number; Facilities Information and Resources Management System (FIRMS) Code; Zone Number; Site Number. Operators must also note whether their background investigation has been completed by CBP, and whether their fingerprints are on file with CBP.

○ *Cartman/Lighterman:* Cartman/Lighterman Identification Number; Customhouse License (CHL) Number; Passport Number; Country of Issuance; Date of Expiration; U.S. Visa Number; Birth Certification Number; Permanent Resident Card Number; Certificate of Naturalization; Certificate of U.S. Citizenship; Re-entry Permit Number (I–327); Refugee Permit Number; Other Identification (such as Military Dependent's Card, Temporary Resident Card, Voter Registration Card). A Cartman/Lighterman must also note whether his or her background investigation has been completed by CBP, and whether his or her fingerprints are on file with CBP.

○ *Carriers:* SCAC; Bond Numbers; Importer Record for Type 2 Bond (if applicable).

○ *Drivers/Crew:* Commercial Driver License (CDL) Number; State/Province of Issuance; Country; whether the Driver has an Enhanced CDL or is HAZMAT endorsed; Full Name; Date of Birth; Gender; Citizenship; Travel Documentation (and Country of Issuance) such as: Passport Number or Permanent Resident Card; or other type of identification including: SENTRI Card; NEXUS [1]; U.S. Visa (non-immigrant or immigrant); Permanent Resident Card; U.S. Alien Registration Card; U.S. Passport Card; DHS Refugee Travel Document; DHS Re-Entry Permit; U.S. Military ID Document; or U.S. Merchant Mariner Document.

Information maintained by ACE as part of the *trade facilitation process* includes:

• Filer Information

○ *Importer of Record Name and Address*—The name and address, including the standard postal two-letter state or territory abbreviation, of the importer of record. The importer of record is defined as the owner or purchaser of the goods, or when designated by the owner, purchaser, or consignee, a licensed customs broker. The importer of record is the individual or firm liable for payment of all duties and meeting all statutory and regulatory requirements incurred as a result of importation, as described in 19 CFR 141.1(b).

○ *Consignee Number*—IRS EIN, SSN, or CBP-assigned number of the consignee. This number must reflect a valid identification number filed with CBP via the CBP Form 5106 or its electronic equivalent.

○ *Importer Number*—The IRS EIN, SSN, or CBP-assigned number of the importer of record.

○ *Reference Number*—The IRS EIN, SSN, or CBP-assigned number of the individual or firm to whom refunds, bills, or notices of extension or suspension of liquidation are to be sent (if other than the importer of record and only when a CBP Form 4811 is on file).

○ *Ultimate Consignee Name and Address*—The name and address of the individual or firm purchasing the merchandise or, if a consigned shipment, to whom the merchandise is consigned.

○ *Broker/Filer Information*—A broker or filer name, address, and phone number.

○ *Broker/Importer File Number*—A broker or importer internal file or reference number.

○ *Bond Agent Information*—Bond agent name, SSN or a surety created identification, and surety name.

○ *Declarant Name, Title, Signature, and Date*—The name, job title, and signature of the owner, purchaser, or agent who signs the declaration. The month, day, and year when the declaration was signed.

○ *Importer Business Description*—Including the Importer Dun & Bradstreet (DUNS) Number and the North American Industry Classification System (NAICS) number for Importer Business.

○ *Senior Officers of the Importing Company*—Information pertaining to Senior Officers of the Importing Company with an importing or financial role in trade transactions: Position title; Name (First, Middle, Last); Business Phone; SSN (Optional); Passport Number (Optional); Passport Country of Issuance (Optional).

○ *Additional Data Elements*—Filers may, on their own initiative, provide additional or clarifying information on the form provided such additional information does not interfere with the reporting of those required data elements.

• Supply Chain Information

○ *Manufacturer Information:*

▪ Manufacturer (or supplier) name;

▪ Manufacturer (or supplier) address;

▪ Foreign manufacturer identification code and/or shipper identification code;

▪ Foreign manufacturer name and/or shipper name; and

▪ Foreign manufacturer address and/or shipper address.

○ *Carrier Information:*

▪ *Importing Carrier*—For merchandise arriving in the U.S. by vessel, CBP records the name of the vessel that transported the merchandise from the foreign port of lading to the first U.S. port of unlading.

• Vessel Identifier Code;
• Vessel Name;
• Carrier Name;
• Carrier Address;
• Carrier codes (non-SSN) (Standard Carrier Agent Code (SCAC) for vessel carriers, International Air Transport Association (IATA) for air carriers);
• Department of Transportation (DOT) number,
• Tax Identification Number;
• DUNS;
• Organizational structure; and
• Insurance information including name of insurer, policy number, date of issuance, and amount.

• The carrier can create users and points of contact, and may also choose to store details associated with the driver and crew, conveyance, and equipment for purposes of expediting the creation of manifests.

▪ *Mode of Transport*—The mode of transportation by which the imported merchandise entered the U.S. port of arrival from the last foreign country.

[1] SENTRI and NEXUS are Trusted Traveler Cards used for expedited border crossing along the southern and northern borders, respectively. *See, http://www.cbp.gov/travel/trusted-traveler-programs.*

The mode of transport may include vessel, rail, truck, air, or mail.

▪ *Export Date*—The month, day, and year on which the carrier departed the last port (or airport, for merchandise exported by air) in the exporting country.

○ Liquidator identification (non-SSN);

○ Seller (full name and address or a widely accepted industry number such as a DUNS number);

○ Buyer (full name and address or a widely accepted industry number such as a DUNS number);

○ Ship to party name;

○ Consolidator (stuffer);

○ Foreign trade zone applicant identification number;

○ Country of origin;

○ Commodity Harmonized Tariff Schedule of the United States (HTSUS) number;

○ Booking party; and

○ Other identification information regarding the party to the transaction.

• Crewmember/Passenger Information

○ Carrier Information—Including vessel flag and vessel name, date of arrival, and port of arrival (CBP Form 5129);

○ Person on arriving conveyance who is in charge;

○ Names of all crew members and passengers;

○ Date of birth of each crew member and passenger;

○ Commercial driver license (CDL)/driver license number for each crew member;

○ CDL state or province of issuance for each crew member;

○ CDL country of issuance for each crew member;

○ Travel document number for each crew member and passenger;

○ Travel document country of issuance for each crew member and passenger;

○ Travel document for state/province of issuance for each crew member and passenger;

○ Travel document type for each crew member and passenger;

○ Address for each crew member and passenger;

○ Gender of each crew member and passenger;

○ Nationality/citizenship of each crew member and passenger; and

○ HAZMAT endorsement for each crew member.

• Federal Employee Information (including CBP and PGA employees)

○ CBP employee names;

○ CBP employee hash identification, SSN, or other employee identification number; and

○ Federal Government employee names, work addresses, work phone numbers, and ACE identification if already an ACE–ITDS user.

• Manifest Information

○ *Bill of Lading (B/L) or Air Waybill (AWB) Number*—The number assigned on the manifest by the international carrier delivering the goods to the United States.

○ *Immediate Transportation Number*—The Immediate Transportation number obtained from the CBP Form 7512, the AWB number from the Transit Air Cargo Manifest (TACM), or Automated Manifest System (AMS) master in-bond (MIB) movement number.

○ *Immediate Transportation Date*—The month, day, and year obtained from the CBP Form 7512, TACM, or AMS MIB record. Note that Immediate Transportation date cannot be prior to import date.

○ *Missing Documents*—Codes that indicate which documents are not available at the time of filing the entry summary.

○ *Foreign Port of Lading*—The five digit numeric code listed in the ''Schedule K'' (Classification of Foreign Ports by Geographic Trade Area and Country) for the foreign port at which the merchandise was actually laden on the vessel that carried the merchandise to the United States.[2]

○ *U.S. Port of Unlading*—The U.S. port code where the merchandise was unladen (or, delivered) from the importing vessel, aircraft, or train.

○ *Location of Goods/General Order (GO) Number*—Also known as a ''container stuffing location,'' the pier or site where the goods are available for examination. For air shipments, this is the flight number.

• CBP Generated Records

○ *Entry Number*—The entry number is a CBP-assigned number that is unique to each Entry Summary (CBP Form 7501).

○ *Entry Type*—Entry type denotes which type of entry summary is being filed (*i.e.,* consumption, information, and warehouse). The sub-entry type further defines the specific processing type within the entry category (*i.e.,* free and dutiable, quota/visa, anti-dumping/countervailing duty, and appraisement).[3]

○ *Summary Date*—The month, day, and year on which the entry summary is filed with CBP. The record copy of the entry summary will be time stamped by the filer at the time of presentation of the entry summary. Use of this field is optional for ABI statement entries. The time stamp will serve as the entry summary date. The filer will record the proper team number designation in the upper right portion of the form above this block (three-character team number code).[4]

○ *Port Code*—The port is where the merchandise was entered under an entry or released under an immediate delivery permit. CBP relies on the U.S. port codes from Schedule D, Customs District and Port Codes, listed in Annex C of the Harmonized Tariff Schedule (HTS).

○ *Entry Date*—The month, day, and year on which the goods are released, except for immediate delivery, quota goods, or when the filer requests another date prior to release.[5] It is the responsibility of the filer to ensure that the entry date shown for entry/entry summaries is the date of presentation (*i.e.,* the time stamp date). The entry date for a warehouse withdrawal is the date of withdrawal.

○ *Manufacturer ID*—This code identifies the manufacture/shipper of the merchandise by a CBP-constructed code. The manufacturer/shipper identification code is required for all entry summaries and entry/entry summaries, including informal entries, filed on the CBP Form 7501.

○ *Notes*—Notations and results of examinations and document review for cleared merchandise.

○ Trade violation statistics.

○ Protest and appeal decision case information.

• Surety and Bond Information

○ *Surety Information*—Full legal name of entity, address.

○ *Surety Number*—A three-digit numeric code that identifies the surety company on the Customs Bond. This code can be found in block 7 of the CBP Form 301, or is available through CBP's automated system to ABI filers, via the importer bond query transaction.

○ *Bond Type*—A three-digit numeric code identifying the following type of bond: U.S. Government or entry types not requiring a bond; Continuous; or Single Transaction.

○ *Additional Bond Information*—All authorized users of bond, bond expiration date.

• Merchandise-Specific Information

○ *Line Number*—A commodity from one country, covered by a line which

[2] The ''Schedule K'' may be retrieved at: *http://www.iwr.usace.army.mil/ndc/wcsc/scheduleK/schedulek.htm.*

[3] Automated Broker Interface (ABI) processing requires an ABI status indicator. This indicator must be recorded in the entry type code block. It is to be shown for those entry summaries with ABI status only.

[4] For ABI entry summaries, the team number is supplied by CBP's automated system in the summary processing output message.

[5] 19 CFR 141.68.

includes a net quantity, entered value, HTS number, charges, rate of duty and tax.

- *Description of Merchandise*—A description of the articles in sufficient detail (*i.e.,* gross weight, manifest quantity, net quantity in HTS units, U.S. dollar value, all other charges, costs, and expenses incurred while bringing the merchandise from alongside the carrier at the port of exportation in the country of exportation and placing it alongside the carrier at the first U.S. port of entry).
- *License Numbers*—For merchandise subject to agriculture licensing.
- *Country of Origin*—The country of origin is the country of manufacture, production, or growth of any article. When merchandise is invoiced in or exported from a country other than that in which it originated, the actual country of origin shall be specified rather than the country of invoice or exportation.
- *Import Date*—The month, day, and year on which the importing vessel transporting the merchandise from the foreign country arrived within the limits of the U.S. port with the intent to unlade.
- *Exporting Country*—The country of which the merchandise was last part of the commerce and from which the merchandise was shipped to the United States.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

IIS derives its authority from 19 U.S.C. 66, 1431, 1448, 1481, 1484, 1505, 1514, 1624, and 2071; 26 U.S.C. 6109(d); 31 U.S.C. 7701(c); section 203 of the Security and Accountability for Every (SAFE) Port Act of 2006 and section 343(a) of the Trade Act of 2002, as amended by the Maritime Transportation Security Act of 2002; Title 19 of the Code of Federal Regulations, including 19 CFR 24.5, 149.3, 101.9, and 103.31(e).

PURPOSE(S):

This system of records allows DHS/CBP to collect and maintain records on all commercial goods imported into the United States, along with carrier, broker, importer, and other ACE–ITDS Portal user account and manifest information. The purpose of this system of records is to track, control, and process all commercial goods imported into the United States. This facilitates the flow of legitimate shipments, and assists DHS/CBP in securing U.S. borders and targeting illicit goods. IIS covers two principle information technology systems: The Automated Commercial System (ACS) and ACE–ITDS. ACS employs multiple modules to receive data transmissions from a variety of parties involved in international commercial transactions and provides DHS/CBP with the capability to track both the transport transactions and the financial transactions associated with the movement of merchandise through international commerce. ACE–ITDS modernizes and enhances trade processing with features that will consolidate and automate border processing. ACE–ITDS serves three sets of core stakeholders: The internal DHS/CBP users, PGAs, and the trade community in the movement of merchandise through international commerce.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the United States Attorneys, or other federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any Component thereof;

2. Any employee or former employee of DHS in his or her official capacity;

3. Any employee or former employee of DHS in his or her individual capacity when DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To appropriate federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, license, or treaty when DHS determines that the information would assist in the enforcement of civil or criminal laws.

H. To a federal, state, or local agency, or other appropriate entity or individual, or through established liaison channels to selected foreign governments, in order to provide intelligence, counterintelligence, or other information for the purposes of intelligence, counterintelligence, or antiterrorism activities authorized by U.S. law, Executive Order, or other applicable national security directive.

I. To the Department of Commerce, United States Census Bureau for statistical analysis of foreign trade data.

J. To a federal agency, pursuant to an International Trade Data System Memorandum of Understanding, consistent with the receiving agency's legal authority to collect information pertaining to and/or regulate transactions in international trade.

K. To a federal, state, local, tribal, territorial, foreign, or international agency, maintaining civil, criminal, or other relevant enforcement information

or other pertinent information, which has requested information relevant or necessary to the requesting agency's hiring or retention of an individual, or issuance of a security clearance, license, contract, grant, or other benefit;

L. To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, in response to a subpoena, or in connection with criminal law proceedings;

M. To third parties during the course of an investigation to the extent necessary to obtain information pertinent to the investigation;

N. To the Department of Justice, Offices of the United States Attorneys or a consumer reporting agency as defined by the Fair Credit Reporting Act, address or physical location information concerning the debtor, for further collection action on any delinquent debt when circumstances warrant;

O. To appropriate federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations when DHS is aware of a need to use relevant data for purposes of testing new technology and systems designed to enhance national security or identify other violations of law;

P. To a former employee of DHS, in accordance with applicable regulations, for purposes of responding to an official inquiry by a federal, state, or local government entity or professional licensing authority; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes when the Department requires information or consultation assistance from the former employee regarding a matter within that person's former area of responsibility;

Q. To an organization or individual in either the public or private sector, either foreign or domestic, when there is a reason to believe that the recipient is or could become the target of a particular terrorist activity or conspiracy, to the extent the information is relevant to the protection of life or property;

R. To paid subscribers, in accordance with applicable regulations, for the purpose of providing access to manifest information as set forth in 19 U.S.C. 1431;

S. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Yes, CBP may disclose, pursuant to 5 U.S.C. 552a(b)(12), to consumer reporting agencies in accordance with the provision of 15 U.S.C. 1681, *et seq.* or the Federal Claims Collection Act of 1966 as amended (31 U.S.C. 3701, *et seq.*). The purpose of this disclosure is to aid in the collection of outstanding debts owed to the Federal Government, typically, to provide an incentive for debtors to repay delinquent Federal Government debts by making these part of their credit records.

Disclosure of records is limited to the individual's name, address, EIN/SSN, and other information necessary to establish the individual's identity; the amount, status, and history of the claim; and the agency or program under which the claim arose. The disclosure will be made only after the procedural requirements of 31 U.S.C. 3711(e) have been followed.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

CBP stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

CBP retrieves records by file identification codes, name or other personal identifier.

SAFEGUARDS:

CBP safeguards records in this system in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. CBP imposes strict controls to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions. The systems maintain a real-time auditing function of individuals who access them. Additional safeguards may vary by Component and program.

RETENTION AND DISPOSAL:

The Importer Security Filing form is retained for fifteen years from date of submission unless it becomes linked to law enforcement action. All other import records contained within IIS are maintained for a period of six years from the date of entry.

Some records are retained online in a system database, while others may be retained in hard copy in ports of entry, as appropriate. Personally identifiable information collected in IIS as part of the regulation of incoming cargo will be retained in accordance with the U.S. Customs Records Schedules approved by the National Archive and Records Administration for the forms on which the data is submitted. This means that cargo, crew, driver, and passenger information collected from a manifest presented in connection with the arrival of a vessel, vehicle, or aircraft will be retained for six years.

Information collected in connection with the submission of a Postal Declaration for a mail importation will be retained for a maximum of six years and three months (as set forth pursuant to NARA Authority N1–36–86–1, U.S. Customs Records Schedule, Schedule 9 Entry Processing, Items 4 and 5).

SYSTEM MANAGER AND ADDRESS:

Director, Integrated Logistic Support, Cargo Systems Program Office, Office of Information Technology, U.S. Customs and Border Protection, who is located at 1801 North Beauregard Street, Alexandria, Virginia 22311.

NOTIFICATION PROCEDURE:

ACE–ITDS portal users may log in to ACE–ITDS to change their profile information and make permissible amendments or corrections to their records. Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the DHS/CBP Freedom of Information Act (FOIA) Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''Contacts.'' If an individual believes more than one Component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief FOIA Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity,

meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. Although no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief FOIA Officer, *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which Component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS Component agency may have responsive records; and

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his or her agreement for you to access his or her records.

Without the above information, the Component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records are obtained through authorized DHS/CBP or other federal agency forms, related documents, or electronic submissions from individuals and/or companies incidental to the conduct of foreign trade and required to administer the transportation and trade laws and regulations of the United States.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

DHS/CBP will not assert any exemptions with regard to information provided by or on behalf of an individual, when requested by the data subject. However, this data may be shared with law enforcement and/or intelligence agencies pursuant to the routine uses identified in the IIS SORN. The Privacy Act requires DHS to maintain an accounting of such disclosures made pursuant to all routine uses. Disclosing the fact that a law enforcement and/or intelligence agency has sought particular records may affect ongoing law enforcement activity. As such, DHS will claim exemption pursuant to 5 U.S.C. 552a(j)(2) from sections (c)(3), (e)(8), and (g)(1) of the Privacy Act, and pursuant to 5 U.S.C. 552a(k)(2) from section (c)(3) of the Privacy Act, from providing an individual the accounting of disclosures, as necessary and appropriate to protect this information.

Dated: July 31, 2015.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2015–19731 Filed 8–14–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0015]

Agency Information Collection Activities: Immigrant Petition for Alien Worker, Form I–140; Extension, Without Change, of a Currently Approved Collection

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

ACTION: 60-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration

(USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until October 16, 2015.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0015 in the subject box, the agency name and Docket ID USCIS–2007–0018. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2007–0018;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2007–0018 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Immigrant Petition for Alien Worker.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–140; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. The information furnished on Form I–140 will be used by USCIS to classify aliens under sections 203(b) (1), 203(b) (2) or 203(b) (3) of the Immigration and Nationality Act (Act).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–140 is 77,149 and the estimated hour burden per response is 1.08 hours (1 hour and 5 minutes).

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 83,321 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $32,132,559.

Dated: August 11, 2015.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2015–20143 Filed 8–14–15; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5832–N–08]

60-Day Notice of Proposed Information Collection: Promise Zones

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 16, 2015.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Bryan Herdliska, Presidential Management Fellow—Promise Zones Initiative Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Bryan Herdliska at *Bryan.n.Herdliska@hud.gov* or telephone 202–402–6758. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Promise Zones.

OMB Approval Number: 2506–0209.

Type of Request: Revision of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: Under the Promise Zones initiative, the federal government will invest and partner with high-poverty urban, rural, and tribal communities to create jobs, increase economic activity, improve educational opportunities, leverage private investment, and reduce violent crime. Additional information about the Promise Zones initiative can be found at *www.hud.gov/promisezones,* and questions can be addressed to *promisezones@hud.gov.* This notice estimates burden for applying for the designation.

Respondents (*i.e.* affected public): Local or Tribal Governments.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Section I—Executive summary	300	1	1	3	900	$40	$36,000
Section II—Abstract	300	1	1	3	900	40	36,000
Section II—Community Eligibility Criteria and Local Leadership Support Documentation	300	1	1	4	1200	40	48,000
Section III—Need	300	1	1	1	300	40	12,000
Section IV—Strategy Part A (Needs and Assets Assessment)	300	1	1	3	900	40	36,000
Section IV—Strategy Part B (Plan)	300	1	1	6	1800	40	72,000
Section IV—Strategy Part C (Sustainability and Financial Feasibility)	300	1	1	3	900	40	36,000
Section IV—Strategy Part D (Resident Engagement Strategy)	300	1	1	3	900	40	36,000
Section V—Capacity and Local Commitment Part A (Partnership Structure and Commitment)	300	1	1	6	1800	40	72,000
Section V—Capacity and Local Commitment Part B (Capacity of Lead Applicant)	300	1	1	6	1800	40	72,000
Section V—Capacity and Local Commitment Part C (Capacity of Implementation Partner Organizations)	300	1	1	6	1800	40	72,000

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Section V—Capacity and Local Commitment Part D (Data and Evaluation Capacity)	300	1	1	3	900	40	36,000
Section V—Capacity and Local Commitment Part E (Resident Engagement Capacity)	300	1	1	3	900	40	36,000
Section V—Capacity and Local Commitment Part F (Strength & Extent of Gov. Commitment)	300	1	1	3	900	40	36,000
Goals and Activities Template	300	1	1	8	2400	40	96,000
Total	300	1	1	61	18300	40	732,000

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 10, 2015.

Harriet Tregoning,

Principal Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2015–20225 Filed 8–14–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[156A2100DD/AAKC001030/ A0A501010.999900.253G]

Advisory Board for Exceptional Children

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of meeting.

SUMMARY: The Bureau of Indian Education (BIE) is announcing that the Advisory Board for Exceptional Children (Advisory Board) will hold its next meeting in Washington, DC. The purpose of the meeting is to meet the mandates of the Individuals with Disabilities Education Act of 2004 (IDEA) for Indian children with disabilities.

DATES: The Advisory Board will meet on Thursday, September 17, 2015, from 8:30 a.m. to 4:30 p.m. and Friday, September 18, 2015, from 8:30 a.m. to 4:30 p.m. Eastern Time. Orientation for new members will be held Wednesday, September 16, 2015, from 9:00 a.m. to 4:00 p.m. Eastern Time.

ADDRESSES: The meetings on Wednesday, September 16, 2015, Thursday, September 17, 2015, and Friday, September 18, 2015, will be held at 1951 Constitution Avenue NW., Room 303–304, Washington, DC 20240; telephone number (202) 208–6123.

FOR FURTHER INFORMATION CONTACT: Ms. Sue Bement, Designated Federal Officer, Bureau of Indian Education, Albuquerque Service Center, Division of Performance and Accountability, 1011 Indian School Road NW., Suite 332, Albuquerque, NM 87104; telephone number (505) 563–5274.

SUPPLEMENTARY INFORMATION: In accordance with the Federal Advisory Committee Act (5 U.S.C. app.), the BIE is announcing that the Advisory Board will hold its next meeting in Washington, DC. The Advisory Board was established under the Individuals with Disabilities Education Act of 2004 (20 U.S.C. 1400 *et seq.*) to advise the Secretary of the Interior, through the Assistant Secretary—Indian Affairs, on the needs of Indian children with disabilities. The meetings are open to the public.

The following items will be on the agenda:

- Introduction of Advisory Board members
- Announcement of Chair Person
- Report from Gloria Yepa, Supervisory Education Specialist, BIE, Division of Performance and Accountability
- Report from BIE Director's Office
- Advisory Board work on Priorities for 2015
- Public Comment (via conference call, September 18, 2015 meeting only *)
- BIE Advisory Board-Advice and Recommendations

* During the September 18, 2015 meeting, time has been set aside for public comment via conference call from 1:30–2:00 p.m. Eastern Time. The call-in information is: Conference Number 1 (888) 417–0376, Passcode 1509140.

Dated: August 12, 2015.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2015–20244 Filed 8–14–15; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[156A2100DD/AAKC001030/ A0A501010.999900 253G]

Revision of Agency Information Collection for the Tribal Reassumption of Jurisdiction Over Child Custody Proceedings

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Affairs (BIA) is seeking comments on the renewal of Office of Management and Budget (OMB) approval for the collection of information for the Tribal Reassumption of Jurisdiction over Child Custody Proceedings, authorized by OMB Control Number 1076–0112. This information collection expires November 30, 2015.

DATES: Submit comments on or before October 16, 2015.

ADDRESSES: You may submit comments on the information collection to Evangeline Campbell, Chief, Division of Human Services, Office of Indian Services, Bureau of Indian Affairs, 1849 C Street NW., MS–4513–MIB, Washington, DC 20240; facsimile: (202) 208–5113; email: *Evangeline.Campbell@bia.gov*.

FOR FURTHER INFORMATION CONTACT: Evangeline Campbell, (202) 513–7621.

SUPPLEMENTARY INFORMATION:

I. Abstract

The BIA is seeking to renew the information collection conducted under 25 CFR 13, which prescribed procedures by which an Indian tribe that occupies a reservation over which a state asserts any jurisdiction pursuant to federal law may reassume jurisdiction over Indian child proceedings as authorized by the Indian Child Welfare Act, Public Law 95–608, 92 Stat. 3069, 25 U.S.C. 1918.

II. Request for Comments

The BIA requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) Ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it has a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. 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.

III. Data

OMB Control Number: 1076–0112.

Title: Tribal Reassumption of Jurisdiction Over Child Custody Proceedings, 25 CFR 13.

Brief Description of Collection: The collection of information will ensure that the provisions of Public Law 95–608 are met. Any Indian Tribe that became subject to State jurisdiction pursuant to the provisions of the Act of August 15, 1953 (67 Stat. 588), as amended by title IV of the Act of April 11, 1968 (82 Stat. 73,78), or pursuant to any other Federal law, may reassume jurisdiction over child custody proceedings. The collection of information provides data that will be used in considering the petition and feasibility of the plan of the Tribe for reassumption of jurisdiction over Indian child custody proceedings. We collect the following information: Full name, address, and telephone; number of petitioning Tribe or Tribes; a Tribal resolution; estimated total number of members in the petitioning Tribe of Tribes with an explanation of how the number was estimated; current criteria for Tribal membership; citation to provision in Tribal constitution authorizing the Tribal governing body to exercise jurisdiction over Indian child custody matters; description of Tribal court; copy of any Tribal ordinances or Tribal court rules establishing procedures or rules for exercise of jurisdiction over child custody matters; and all other information required by 25 CFR 13.11. Response is required to obtain or retain a benefit.

Type of Review: Extension without change of currently approved collection.

Respondents: Federally recognized Tribes who submit Tribal reassumption petitions for review and approval by the Secretary of the Interior.

Number of Respondents: 1, on average.

Frequency of Response: Annually.

Estimated Time per Response: 8 hours.

Estimated Total Annual Hour Burden: 8 hours.

Estimated Total Annual Non-Hour Dollar Cost: $0.

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2015–20139 Filed 8–14–15; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2015–0093; MMAA104000]

Outer Continental Shelf, Gulf of Mexico, Oil and Gas Lease Sale, Central Planning Area Lease Sale 247

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of Intent to Prepare a Supplemental Environmental Impact Statement and an Announcement of Scoping Meetings and Comment Period for Proposed Gulf of Mexico Outer Continental Shelf Oil and Gas Central Planning Area Lease Sale 247.

SUMMARY: Consistent with the regulations implementing the National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et seq.),* BOEM is announcing its intent to prepare a Supplemental Environmental Impact Statement (EIS) for proposed Gulf of Mexico Outer Continental Shelf (OCS) Central Planning Area (CPA) Oil and Gas Lease Sale 247 (CPA 247 Supplemental EIS). The CPA 247 Supplemental EIS will expand or update the environmental and socioeconomic analyses in: *Gulf of Mexico OCS Oil and Gas Lease Sales: 2012–2017; Western Planning Area Lease Sales 229, 233, 238, 246, and 248; Central Planning Area Lease Sales 227, 231, 235, 241, and 247, Final Environmental Impact Statement* (2012–2017 WPA/CPA Multisale EIS); *Gulf of Mexico OCS Oil and Gas Lease Sales: 2013–2014; Western Planning Area Lease Sale 233; Central Planning Area Lease Sale 231, Final Supplemental Environmental Impact Statement* (WPA 233/CPA 231 Supplemental EIS); *Gulf of Mexico OCS Oil and Gas Lease Sales: 2015–2017; Central Planning Area Lease Sales 235, 241, and 247, Final Supplemental EIS* (CPA 235/241/247 Supplemental EIS); and *Central Planning Area Lease Sales 241 and 247 and Eastern Planning Area Lease Sale 226, Final Supplemental EIS* (CPA 241/247 and EPA 226 Supplemental EIS).

The CPA 247 Supplemental EIS will supplement the NEPA documents cited above in order to consider new circumstances and information arising from, among other things, the *Deepwater Horizon* explosion, oil spill, and response. It will focus on updating the baseline conditions and any new information on the potential environmental effects of oil and natural gas leasing, exploration, development, and production in the CPA identified through the Area Identification procedure as the proposed lease sale area. In addition to the no action alternative (*i.e.,* canceling a proposed lease sale), other alternatives may be considered for the proposed CPA lease sales, such as deferring certain areas from the proposed lease sale area.

DATES: Comments on the scope of the CPA 247 Supplemental EIS should be submitted by September 16, 2015.

FOR FURTHER INFORMATION CONTACT: For information on the CPA 247 Supplemental EIS or the submission of comments, please contact Mr. Gary D. Goeke, Chief, Environmental Assessment Section, Office of Environment (GM 623E), BOEM, Gulf of Mexico OCS Region, 1201 Elmwood

Park Boulevard, New Orleans, LA 70123–2394, telephone 504–736–3233.

SUPPLEMENTARY INFORMATION: On August 27, 2012, the Secretary of the Interior approved the OCS Oil and Gas Leasing Program: 2012–2017 (2012–2017 Five Year Program). This Supplemental EIS will consider the last CPA sale for this 2012–2017 Five Year Program. Proposed CPA Lease Sale 247 is tentatively scheduled to be held in 2017.

Scoping Process: This Notice of Intent (NOI) serves to announce the scoping process for identifying issues for the CPA 247 Supplemental EIS. Throughout the scoping process, Federal, State, Tribal, and local governments and the general public have the opportunity to help BOEM determine significant resources and issues, impacting factors, reasonable alternatives, and potential mitigating measures to be analyzed in the CPA 247 Supplemental EIS, and to provide additional information. BOEM will also use the scoping process to inform the Section 106 consultation process of the National Historic Preservation Act (16 U.S.C. 470f), as provided for in 36 CFR 800.2(d)(3). Pursuant to the regulations implementing the procedural provisions of NEPA, the BOEM will hold public scoping meetings in Alabama, Louisiana and Mississippi on the CPA 247 Supplemental EIS. The purpose of these meetings is to solicit comments on the scope of the CPA 247 Supplemental EIS. BOEM's scoping meetings will be held at the following places and times:

- Mobile, Alabama: Tuesday, September 1, 2015, Hilton Garden Inn Mobile West, 828 West I–65 Service Road South, Mobile, Alabama 36609, one meeting beginning at 4:00 p.m. CDT;
- Gulfport, Mississippi: Wednesday, September 2, 2015, Courtyard by Marriott, Gulfport Beachfront MS Hotel, 1600 East Beach Boulevard, Gulfport, Mississippi 39501, one meeting beginning at 6:00 p.m. CDT; and
- New Orleans, Louisiana: Thursday, September 3, 2015, Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123, one meeting beginning at 1:00 p.m. CDT.

Cooperating Agency: BOEM invites other Federal, State, Tribal, and local governments to consider becoming cooperating agencies in the preparation of the CPA 247 Supplemental EIS. We invite qualified government entities to inquire about cooperating agency status for the CPA 247 Supplemental EIS. Following the guidelines from the Council on Environmental Quality (CEQ), qualified agencies and governments are those with ''jurisdiction by law or special expertise.'' Potential cooperating agencies should consider their authority and capacity to assume the responsibilities of a cooperating agency and should remember that an agency's role in the environmental analysis neither enlarges nor diminishes the final decision making authority of any other agency involved in the NEPA process. Upon request, BOEM will provide potential cooperating agencies with a written summary of ground rules for cooperating agencies, including time schedules and critical action dates, milestones, responsibilities, scope and detail of cooperating agencies' contributions, and availability of predecisional information. BOEM anticipates this summary will form the basis for a Memorandum of Agreement between BOEM and any cooperating agency pursuant to 43 CFR 46.225. Agencies should also consider DOI's implementing regulation at 43 CFR part 46 and the ''Factors for Determining Cooperating Agency Status'' in Attachment 1 to CEQ's January 30, 2002, Memorandum for the Heads of Federal Agencies: Cooperating Agencies in Implementing the Procedural Requirements of the National Environmental Policy Act. The CEQ documents are available at the following location on the Internet: *http://energy.gov/sites/prod/files/nepapub/nepa_documents/RedDont/G-CEQCoopAgenciesImplem.pdf.*

BOEM, as the lead agency, will not provide financial assistance to cooperating agencies. Even if an organization is not a cooperating agency, opportunities will exist to provide information and comments to BOEM during the normal public input stages of the EIS process. For further information about cooperating agencies, please contact Mr. Gary D. Goeke at (504) 736–3233.

Comments: All interested parties, including Federal, State, Tribal, and local governments, and other organizations and members of the public, may submit written comments on the scope of the CPA 247 Supplemental EIS, significant issues that should be addressed, alternatives that should be considered, potential mitigating measures, and the types of oil and gas activities of interest in the proposed CPA lease sale area. BOEM is also seeking public comment and input regarding the identification of historic properties or potential effects, as defined by the National Historic Preservation Act, to historic properties from the proposed action. Written comments may be submitted in one of the following ways:

1. Federal eRulemaking Portal: *http://www.regulations.gov.* In the field entitled ''Search'' enter ''BOEM'' and then click ''search.'' Under ''Comment Period'' select ''Open'' and under ''Document Type'' select ''Notice''. Choose the ''Notice'' for ''Oil and Gas Lease Sales: Gulf of Mexico, Outer Continental Shelf; Central Planning Area Lease Sale 247.'' Follow the instructions to submit public comments and view supporting and related materials available for this notice;

2. U.S. mail in an envelope labeled ''Scoping Comments for the CPA 247 Supplemental EIS'' and mailed (or hand delivered) to Mr. Gary D. Goeke, Chief, Environmental Assessment Section, Office of Environment (GM 623E), BOEM, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394. Comments must be postmarked by the last day of the comment period to be considered. As noted in the ''Dates'' section above, the comment period ends on *September 16, 2015*.

3. Via electronic mail to email address: *cpa247@boem.gov.*

Petitions, although accepted, do not generally provide useful information to assist in the development of alternatives, resources, and issues to be analyzed, or impacting factors. BOEM does not consider anonymous comments; please include your name and address as part of your submittal. BOEM makes all comments, including the names and addresses of respondents, available for public review during regular business hours. 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: This NOI to prepare a Supplemental EIS is published pursuant to the regulations (40 CFR 1501.7 and 43 CFR 46.435) implementing the provisions of NEPA.

Dated: August 11, 2015.

Walter D. Cruickshank,

Deputy Director, Bureau of Ocean Energy Management.

[FR Doc. 2015–20262 Filed 8–13–15; 11:15 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1 SS08011000SX064A000156S180110; S2D2SS08011000SX064A00015X501520]

Notice of Proposed Information Collection; Request for Comments for 1029–0119

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

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to seek approval to continue the collection of information for the contractor eligibility, and the Abandoned Mine Land (AML) Contractor Information form. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned clearance number 1029–0119.

DATES: Comments on the proposed information collection must be received by October 16, 2015, to be assured of consideration.

ADDRESSES: Comments may be mailed to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease, at (202) 208–2783 or by email at *jtrelease@osmre.gov.*

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. This notice identifies information collection that OSM will be submitting to OMB for approval. This collection is contained in 30 CFR 874.16 and the Abandoned Mine Land Contractor Information form. OSM will request a 3-year term of approval for each information collection activity. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection is 1029–0119. Responses are required to obtain a benefit.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

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.

Title: 30 CFR 874.16—Contractor eligibility, and the AML Contractor Information form.

OMB Control Number: 1029–0119.

Summary: 30 CFR 874.16 requires that every successful bidder for an AML contract must be eligible under 30 CFR 773.15(b)(1) at the time of contract award to receive a permit or conditional permit to conduct surface coal mining operations. Further, the regulation requires the eligibility to be confirmed by OSMRE's automated AVS and the contractor must be eligible under the regulations implementing Section 510(c) of the Surface Mining Act to receive permits to conduct mining operations. The AML Contractor Information form provides a tool for OSM and the States/Indian tribes to help them prevent persons with outstanding violations from conducting further mining or AML reclamation activities in the State.

Bureau Form Number: None.

Frequency of Collection: Once per contract.

Description of Respondents: AML contract applicants and State and tribal AML authorities.

Total Annual Responses: 247 bidders and 93 State responses.

Total Annual Burden Hours: 205.

Dated: August 6, 2015.

Harry J. Payne,

Chief, Division of Regulatory Support.

[FR Doc. 2015–20216 Filed 8–14–15; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–468 and 731–TA–1166–1167 (Review)]

Certain Magnesia Carbon Bricks from China and Mexico; Correction to Notice of Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: In a notice published in the **Federal Register** on August 3, 2015 (80 FR 46050), the Commission published a notice of institution of five-year reviews concerning the antidumping and countervailing duty orders on certain magnesia carbon bricks from China and Mexico with incorrect investigation numbers. The correct investigation numbers are as follows: Investigation Nos. 701–TA–468 and 731–TA–1166–1167 (Review).

DATES: *Effective Date:* August 3, 2015.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: August 11, 2015.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2015–20181 Filed 8–14–15; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0061]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Approval of an Extension of a Currently Approved Collection; Request To Change III/NGI Base Identifier(s) (1–542)

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) Division, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the 80 FR 33290, on June 11, 2015, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for an additional days until September 16, 2015:

If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Gerry Lynn Brovey, Supervisory Information Liaison Specialist, FBI, CJIS, Resources Management Section, Administrative Unit, Module C–2, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306 (facsimile: 304–625–5093). Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Request to Change III/NGI Base Identifier(s).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* 1–542.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: City, county, state, federal and tribal law enforcement agencies. This collection is needed to report completion of an identity history summary. Acceptable data is stored as part of the Next Generation Identification (NGI) system of the FBI.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that approximately 114,000 agencies will complete each form within fifteen minutes.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 28,500 total annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: August 11, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–20128 Filed 8–14–15; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Oil Pollution Act

On August 11, 2015, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of Texas in the lawsuit entitled *United States and the State of Texas* v. *Koch Pipeline Company, L.P.,* Civil Action No. *SA–15–CV–676*.

In this action, the United States and the State of Texas, pursuant to Section 1002 of the Oil Pollution Act of 1990, seek natural resource damages, including past and future administrative and assessment costs, arising out of the unauthorized discharge of crude oil into Marcelinas Creek, a navigable water of the United States and the State of Texas, from Defendant's former crude oil receiving station in Karnes County, Texas, on October 18, 1998.

The proposed Consent Decree requires Defendant to pay the sum of $770,000, an amount which will: (1) Fund the restoration option selected by the federal and state trustees, (2) reimburse the trustees for their past assessment costs, and (3) provide for future administrative and assessment costs associated with implementation of the restoration plan. The United States and the State of Texas provide covenants not to sue Defendant pursuant to the Oil Pollution Act, 33 U.S.C. 2701 *et seq.,* and the Clean Water Act, 33 U.S.C. 1251 *et seq.,* for natural resource damages resulting from the spill.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the State of Texas* v. *Koch Pipeline Company, L.P.,* D.J. Ref. No. 90–5–1–1–10848. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by first class mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By first class mail.	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined

and downloaded at this Justice Department Web site: *http://www.justice.gov/enrd/consent-decrees*. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $5.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Thomas P. Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–20215 Filed 8–14–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Statutory Reconsideration of Petitions for Trade Adjustment Assistance

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: On June 29, 2015, President Obama signed into law the Trade Adjustment Assistance Reauthorization Act of 2015 (TAARA 2015), title IV of the Trade Preferences Extension Act of 2015, Public Law 114–27. In accordance with Section 405(a) of TAARA 2015, which amended the Trade Act of 1974, Public Law 93–618 (''the Trade Act''), the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration (OTAA) has taken the following action for petitions that were filed with the Secretary of Labor under section 221(a) of the Trade Act on or after January 1, 2014, and before June 29, 2015, and are identified in the Appendices to this notice.

OTAA has reopened investigations of petitions identified in Appendix A to reconsider all negative determinations on petitions filed on or after January 1, 2014, and before June 29, 2015, and will further investigate those petitions to determine whether the workers are eligible to apply for adjustment assistance under the provisions of section 222 of the Trade Act in effect on June 29, 2015, which were in effect before January 1, 2014. If eligible under these requirements, OTAA will certify the group of workers as eligible to apply for adjustment assistance under title II of the Trade Act, as amended by TAARA 2015.

OTAA also is continuing to investigate those petitions identified in Appendix B for which no determination was issued before June 29, 2015, to determine whether the workers are eligible to apply for adjustment assistance under the provisions of section 222 of the Trade Act in effect on June 29, 2015, which were in effect before January 1, 2014. If eligible under these requirements, OTAA will certify the group of workers as eligible to apply for adjustment assistance under title II of the Trade Act.

Further, worker groups that did not submit petitions between January 1, 2014 and June 29, 2015, but wish to be considered under the group eligibility for workers based on the 2015 Program may file a new petition within 90 days of enactment of the new 2015 law which was signed by President Barak Obama on June 29, 2015. This would include service sector workers as well as worker groups whose jobs are adversely affected by trade from countries that are not parties to Free Trade Agreements (FTAs) with the United States, including China and India. While all petitions filed on and after June 29, 2015, will be investigated under the 2015 Program worker group eligibility criteria, the TAARA 2015 provides that for petitions filed by MIDNIGHT (12:00 AM EASTERN TIME), SUNDAY, SEPTEMBER 27, 2015, that are certified, the certification will cover all members of the worker group who are separated or threatened with separations during the period beginning January 1, 2014, instead of a beginning date of no more than one year before the date of the petition, and generally ending two years after the date of certification. Each of those certifications will describe the worker group and specify the January 1, 2014, beginning date and the ending dates of the certification period.

APPENDIX A—LIST OF STATUTORY RECONSIDERATION OF NEGATIVE DETERMINATIONS UNDER REVERSION 2014

TA–W	Subject firm (petitioners)	Location	Date of petition filing
85001	Boehringer Ingelheim Chemicals, Inc. (BICI) (State/One-Stop)	Petersburg, VA	1/6/2014
85003	Warner Brothers Home Entertainment, Inc. (Workers)	Burbank, CA	1/6/2014
85004	Resorts World Casino (Workers)	Queens, NY	1/7/2014
85009	Atos SE (State/One-Stop)	New York, NY	1/9/2014
85010	The Smithfield Packing Company, Incorporated (State/One-Stop)	Landover, MD	1/10/2014
85012	SANYO Solar (USA) LLC (Company)	Carson, CA	1/13/2014
85013	TRW Integrated Chassis Systems, LLC (Workers)	Saginaw, MI	1/13/2014
85015	Leviton Manufacturing Company, Inc. (Workers)	West Jefferson, NC	1/14/2014
85016	Mid-West Textile (Workers)	El Paso, TX	1/15/2014
85018	IBM Corporation (State/One-Stop)	Endicott, NY	1/16/2014
85019	Salience Insight, Inc. (Workers)	Berlin, NH	1/17/2014
85020	FCI USA LLC (Company)	Etters, PA	1/17/2014
85022	Intrepid Potash Inc. (Workers)	Denver, CO	1/22/2014
85025	Philips Electronics North America Corporation (Workers)	Bothell, WA	1/22/2014
85025A	Philips Electronics North America Corporation (Workers)	Andover, MA	1/22/2014
85025B	Philips Electronics North America Corporation (Company)	Pittsburgh, PA	1/22/2014
85027	CHF Industries, Inc. (State/One-Stop)	Loris, SC	1/22/2014
85029	Oldcastle Building Envelope (Company)	Everett, WA	1/23/2014
85031	Iron Mountain Information Management, LLC (State/One-Stop)	Boston, MA	1/23/2014
85035	Hewlett Packard Company (State/One-Stop)	Ft. Collins, CO	1/27/2014
85035A	Hewlett Packard Company (State/One-Stop)	Ft. Collins, CO	1/27/2014
85035B	Hewlett Packard Company (State/One-Stop)	Ft. Collins, CO	1/27/2014
85035C	Hewlett Packard Company (State/One-Stop)	Boise, ID	1/27/2014
85036	Kelsey-Hayes Company (Workers)	Sterling Heights, MI	1/28/2014
85037	Honeywell (Workers)	Irving, TX	1/28/2014

APPENDIX A—LIST OF STATUTORY RECONSIDERATION OF NEGATIVE DETERMINATIONS UNDER REVERSION 2014—Continued

TA–W	Subject firm (petitioners)	Location	Date of petition filing
85038	Tate and Kirlin Associates, Inc. (Workers)	Philadelphia, PA	1/29/2014
85039	Freescale Semiconductor, Inc. (State/One-Stop)	Austin, TX	1/29/2014
85040	S&S Transportation, Inc. (Company)	Lincoln, ME	1/29/2014
85045	I2S, LLC (Workers)	Yalesville, CT	1/31/2014
85046	AIG Claims Inc. (Workers)	Houston, TX	1/31/2014
85048	British Telecommunications (State/One-Stop)	Princeton, NJ	2/3/2014
85050	Carthage Area Hospital (Company)	Carthage, NY	2/3/2014
85051	VEC Technology, LLC (Workers)	Greenville, PA	2/5/2014
85052	Symantec Corporation (State/One-Stop)	Beaverton, OR	2/5/2014
85055	Ace Global (State/One-Stop)	Phoenix, AZ	2/6/2014
85057	Hyosung USA, Inc. (State/One-Stop)	Utica, NY	2/7/2014
85062	Computer Sciences Corporation (Workers)	El Segundo, CA	2/11/2014
85064	Southside Manufacturing (State/One-Stop)	Blairs, VA	2/11/2014
85066	SunEdison, Inc. (Workers)	St. Peters, MO	2/12/2014
85067	FLSmidth USA, Inc. (Company)	Meridian, ID	2/12/2014
85068	GE Hitachi Nuclear Energy (Workers)	Canonsburg, PA	2/12/2014
85069	Allstate Insurance (State/One-Stop)	Roanoke, VA	2/12/2014
85073	Symak Sales Co. Inc. (Company)	Plattsburgh, NY	2/18/2014
85075	Duro Textiles, LLC (State/One-Stop)	Fall River, MA	2/19/2014
85076	Support.com, Inc. (Union)	Redwood City, CA	2/19/2014
85077	Caterpillar, Inc. (State/One-Stop)	Pulaski, VA	2/19/2014
85078	Sun-Times Media Production, LLC (Workers)	Chicago, IL	2/20/2014
85081	Larsen Manufacturing Southwest (State/One-Stop)	El Paso, TX	2/20/2014
85083	TransTrade Operators, Inc. (Union)	DFW Airport, TX	2/20/2014
85086A	Bayer CropScience LP (State/One-Stop)	Institute, WV	2/21/2014
85089	Bank of America (State/One-Stop)	San Jose, CA	2/24/2014
85090	Pixel Playground, Inc. (State/One-Stop)	Woodland Hills, CA	2/24/2014
85093	Specialty Foods Group, Inc. (Workers)	Chicago, IL	2/26/2014
85097	SuperMedia Services LLC (State/One-Stop)	Middleton, MA	2/26/2014
85099	Harrington Tool Company (State/One-Stop)	Ludington, MI	2/26/2014
85101	HelioVolt Corporation (Company)	Austin, TX	2/26/2014
85102	Northport USA LLC (State/One-Stop)	Wilkes Barre, PA	2/28/2014
85103	Guru Denim, Inc. (Union)	Vernon, CA	2/28/2014
85107	Honeywell Federal Manufacturing & Technologies LLC (Union)	Kansas City, MO	3/4/2014
85109	Sharp Manufacturing Co. of America (SMCA) (Workers)	Memphis, TN	3/4/2014
85111	Windstream Corporation (Workers)	Dalton, GA	3/4/2014
85112	UL, LLC (Union)	Melville, NY	3/4/2014
85113	Rocktenn Company (Workers)	Grand Prairie, TX	3/4/2014
85114	Predator Systems, Inc. (State/One-Stop)	Boca Raton, FL	3/4/2014
85115	Hoax Films, LLC (State/One-Stop)	Los Angeles, CA	3/5/2014
85116	Reebok International LTD. (State/One-Stop)	Canton, MA	3/5/2014
85119	Hewlett Packard Company (Union)	Palo Alto, CA	3/5/2014
85121	Roseburg Forest Products Company (State/One-Stop)	Riddle, OR	3/6/2014
85122	Bimbo Bakeries USA, Inc. (Company)	Wichita, KS	3/6/2014
85123	Elsevier, Inc. (Company)	San Diego, CA	3/6/2014
85125	Source Medical (Workers)	Rome, GA	3/7/2014
85127	Mid Atlantic Manufacturing & Hydraulics, Inc. (State/One-Stop)	Rural Retreat, VA	3/10/2014
85129	Windstream Corporation (State/One-Stop)	Harrison, AR	3/10/2014
85131	Mitsubishi Nuclear Energy Systems, Inc. (Company)	Irving, TX	3/11/2014
85137	LexisNexis (Company)	Miamisburg, OH	3/12/2014
85137A	LexisNexis (Company)	Albany, NY	3/12/2014
85137B	LexisNexis (Company)	Charlotteville, VA	3/12/2014
85137C	LexisNexis (Company)	Colorado Spings, CO	3/12/2014
85137D	LexisNexis (Company)	Dayton, OH	3/12/2014
85137E	LexisNexis (Company)	Springfield, OH	3/12/2014
85137F	LexisNexis (Company)	New Providence, NJ	3/12/2014
85137G	LexisNexis (Company)	New York, NY	3/12/2014
85137H	LexisNexis (Company)	San Francisco, CA	3/12/2014
85137I	LexisNexis (Workers)	Orem, UT	3/12/2014
85138	ARRIS Group, Inc. (State/One-Stop)	State College, PA	3/12/2014
85139	Syncreon US Inc. (State/One-Stop)	Sterling Heights, MI	3/12/2014
85144	IP & Science (Patent Payments) (Workers)	Bingham Farms, MI	3/13/2014
85145	AXA Equitable Life Insurance Company (State/One-Stop)	Charlotte, NC	3/13/2014
85148	Laserwords U.S. Inc. (Workers)	Lewiston, ME	3/14/2014
85150	Clear (State/One-Stop)	Palatine, IL	3/18/2014
85153	Staples, Inc. (State/One-Stop)	Framingham, MA	3/18/2014
85154	Xerox Imager Delivery Center (Workers)	El Segundo, CA	3/18/2014
85155	DMI Edon, LLC (Workers)	Edon, OH	3/18/2014
85158	Cox Communications California LLC (Workers)	Rancho Santa Margarita, CA	3/19/2014

APPENDIX A—LIST OF STATUTORY RECONSIDERATION OF NEGATIVE DETERMINATIONS UNDER REVERSION 2014—Continued

TA–W	Subject firm (petitioners)	Location	Date of petition filing
85159	Seagate Technologies PLC (Workers)	Shakopee, MN	3/19/2014
85159A	Seagate Technologies PLC (Workers)	Bloomington, MN	3/19/2014
85163	Creative Apparel Associates LLC (State/One-Stop)	Fort Kent, ME	3/20/2014
85165	Esterline Memtron Input Components (Workers)	Frankenmuth, MI	3/21/2014
85166	Hartford Fire Insurance Company (Workers)	Hartford, CT	3/21/2014
85167	Dell Marketing L.P. and Dell USA LP (Workers)	Plano, TX	3/21/2014
85173	Xerox State and Local Solutions, Inc. (Union)	Waite Park, MN	3/25/2014
85174	AT&T Corp. (Workers)	Pittsburgh, PA	3/25/2014
85175	Virtual Training Company, Inc. (Workers)	Stephens City, VA	3/25/2014
85180	Hewlett Packard (Union)	Boise, ID	3/27/2014
85181	Innovative Hearth Products, LLC (State/One-Stop)	Union City, TN	3/27/2014
85182	M*Modal Services, Ltd. (Workers)	Franklin, TN	3/28/2014
85183	Hyundai America Shipping Agency, Inc. (State/One-Stop)	Itasca, IL	3/28/2014
85184	Oracle America, Inc. (State/One-Stop)	Broomfield, CO	3/28/2014
85185	Broadridge Financial Solutions Inc. (Company)	Jersey City, NJ	3/31/2014
85190	DNP Electronics America, LLC (Workers)	Chula Vista, CA	4/1/2014
85194	Med-Fit Systems, Inc. (Workers)	Independence, VA	4/2/2014
85195	Stream Global Services, Inc. (State/One-Stop)	Sergeant Bluff, IA	4/2/2014
85197	Bimbo Bakeries, USA, Inc. (Workers)	Bay Shore, NY	4/2/2014
85203	Citigroup Technology, Inc. (“Cti”) (State/One-Stop)	Tampa, FL	4/3/2014
85205	Digital Domain 3.0, Inc. (Company)	Los Angeles, CA	4/3/2014
85206	OVUS Technologies LLC (Union)	Dallas, TX	4/3/2014
85208	Lockheed Martin Ship and Air Services (Workers)	Akron, OH	4/4/2014
85217	JP Morgan Chase and Company (State/One-Stop)	Florence, SC	4/10/2014
85220	SunTrust Mortgage, Inc. (Union)	Atlanta, GA	4/11/2014
85222	Air System Components, Inc. (State/One-Stop)	Ponca City, OK	4/11/2014
85228	Nilfisk-Advance, Inc. (Union)	Plymouth, MN	4/15/2014
85229	Trane U.S., Inc. (Workers)	La Crosse, WI	4/15/2014
85231	Convergys (State/One-Stop)	Denver, CO	4/15/2014
85232	Dex Media, Inc. (Workers)	Erie, PA	4/15/2014
85237	Hyundia Regional Customer Service Center (State/One-Stop)	Charlotte, NC	4/15/2014
85239	Robert Bosch Tool Corporation, Inc. (Union)	Mount Prospect, IL	4/16/2014
85241	Institute Career Development (Workers)	Merrillville, IN	4/17/2014
85245	Detroit Tool & Engineering, Inc. (Workers)	Lebanon, MO	4/18/2014
85247	MoneyGram Payment Systems. Inc. (Workers)	Brooklyn Center, MN	4/21/2014
85249	Mitel, Inc. (Workers)	Mesa, AZ	4/21/2014
85250	Dell Marketing L.P. and Dell USA LP (Workers)	Round Rock, TX	4/21/2014
85251	Hewlett Packard Company (Workers)	Boise, ID	4/21/2014
85251A	Hewlett Packard Company (Workers)	Boise, ID	4/21/2014
85251B	Hewlett Packard Company (Company)	Boise, ID	4/21/2014
85254	Sony Electronics, Inc. (Company)	Carson, CA	4/22/2014
85254A	Sony Electronics, Inc. (Company)	Los Angeles, CA	4/22/2014
85254B	Sony Electronics, Inc. (Company)	Los Angeles, CA	4/22/2014
85254C	Sony Electronics, Inc. (Company)	San Diego, CA	4/22/2014
85254D	Sony Electronics, Inc. (Company)	San Jose, CA	4/22/2014
85254E	Sony Electronics, Inc. (Company)	Fort Myers, FL	4/22/2014
85254F	Sony Electronics, Inc. (Company)	Honolulu, HI	4/22/2014
85254G	Sony Electronics, Inc. (Company)	Itasca, IL	4/22/2014
85254H	Sony Electronics, Inc. (Company)	Bloomington, MN	4/22/2014
85254I	Sony Electronics, Inc. (Company)	Park Ridge, NJ	4/22/2014
85254J	Sony Electronics, Inc. (Company)	Laredo, TX	4/22/2014
85254K	Sony Electronics, Inc. (Company)	Laredo, TX	4/22/2014
85254L	Sony Electronics, Inc. (Company)	Redmond, WA	4/22/2014
85254M	Sony Electronics, Inc. (Company)	Middleton, WI	4/22/2014
85261C	Hibu Inc. (State/One-Stop)	Spokane Valley, WA	4/24/2014
85263	SC&H Group (State/One-Stop)	Sparks, MD	4/24/2014
85264	Cloud Cap Technology, Inc. (State/One-Stop)	Hood River, OR	4/25/2014
85267	Support.com, Inc. (Workers)	Redwood City, CA	4/28/2014
85269	International Flight Training Academy, Inc. (State/One-Stop)	Bakersfield, CA	4/29/2014
85273	Destination Rewards, Inc. (State/One-Stop)	Boca Raton, FL	4/29/2014
85274	Eternal Fortune Fashion LLC (Workers)	New York, NY	4/30/2014
85277	Aegis Media Americas (Union)	Boston, MA	5/1/2014
85278	Swan Dyeing and Printing Corporation (State/One-Stop)	Fall River, MA	5/1/2014
85280	ClearEdge Power LLC (State/One-Stop)	South Windsor, CT	5/2/2014
85285	Wave Accounting, Inc. (Delaware) (State/One-Stop)	Wilmington, DE	5/5/2014
85285A	Wave Accounting, Inc. (Delaware) (State/One-Stop)	Webster, NY	5/5/2014
85287	Quad/Graphics Marketing, LLC (State/One-Stop)	Marengo, IA	5/6/2014
85288	Automated Solutions, Inc. (State/One-Stop)	Knoxville, AR	5/7/2014
85290	Rigaku Innovative Technologies, Inc. (State/One-Stop)	Auburn Hills, MI	5/7/2014

APPENDIX A—LIST OF STATUTORY RECONSIDERATION OF NEGATIVE DETERMINATIONS UNDER REVERSION 2014—Continued

TA–W	Subject firm (petitioners)	Location	Date of petition filing
85291	ProLogix Distribution Services, East (State/One-Stop)	Spring Arbor, MI	5/7/2014
85292	Dix Digital Prepress, Inc. (Workers)	Cicero, NY	5/7/2014
85294	Pitney Bowes Inc. (State/One-Stop)	Spokane, WA	5/7/2014
85295	Bimbo Bakeries USA, Inc. (State/One-Stop)	Sioux City, IA	5/8/2014
85296	ArcSoft, Inc. (Workers)	Fremont, CA	5/8/2014
85300	Sensormatic Electronics LLC (Workers)	Boca Raton, FL	5/9/2014
85301	Citigroup Technology, Inc. (“CTI”) (Company)	Warren, NJ	5/13/2014
85317	Child Care Services (Workers)	Courtland, MS	5/20/2014
85321	JP Morgan Chase and Company (Company)	Florence, SC	5/20/2014
85323	Aviat Networks (State/One-Stop)	Santa Clara, CA	5/21/2014
85325	Tata Technologies, Inc. (Workers)	Auburn Hills, MI	5/21/2014
85331	Music Group Services US (Workers)	Bothell, WA	5/22/2014
85333	IQE North Carolina (Workers)	Greensboro, NC	5/23/2014
85334	Cubix Software Ltd., Inc. (Workers)	Longview, TX	5/27/2014
85337	Dell Marketing L.P. And Dell USA LP (Workers)	Plano, TX	5/28/2014
85339	Freescale Semiconductor, Inc. (Company)	Austin, TX	5/29/2014
85342	North Cascade Mechanical, LLC (Workers)	Blaine, WA	5/30/2014
85343	Risk Specialists Insurance Companies Insurance Agency, Inc. (Workers).	Houston, TX	5/30/2014
85348	Center Partners, Inc. (Workers)	Idaho Falls, ID	5/30/2014
85350	Computer Sciences Corporation (CSC) (State/One-Stop)	Blythewood, SC	6/2/2014
85351	Gold Inc. D/B/A Goldbug, Inc. (State/One-Stop)	Aurora, CO	6/2/2014
85352	Pioneer Hi-Bred, International—Mt. Pleasant (State/One-Stop)	Mount Pleasant, IA	6/2/2014
85355	Chevron Mining, Inc. (Company)	Questa, NM	6/4/2014
85362	Catawissa Wood and Components, Inc. (Union)	Elysburg, PA	6/6/2014
85371	Contacts Metals and Welding, Inc. (State/One-Stop)	Indianapolis, IN	6/12/2014
85373	General Electric International, Inc. (Workers)	Plainville, CT	6/12/2014
85375	Caterpillar, Inc. (State/One-Stop)	Pearisburg, VA	6/13/2014
85377	Chemtrade Chemicals US LLC (Workers)	Parsippany, NJ	6/16/2014
85381	Gamestop Texas, Ltd. (Workers)	Grapevine, TX	6/19/2014
85382	Baldor Electric Company (Workers)	Fort Smith, AR	6/19/2014
85383	Knowledge Universe—U.S. (State/One-Stop)	Portland, OR	6/19/2014
85384	Verizon California, Inc. (Company)	Long Beach, CA	6/18/2014
85386	Covidien LP (Union)	Mansfield, MA	6/19/2014
85387	John Deere Harvester Works (Workers)	East Moline, IL	6/23/2014
85388	JPMorgan Chase & Co. (Company)	Florence, SC	6/23/2014
85393	Chemtura Corporation (Workers)	West Lafayette, IN	6/25/2014
85394	Merck Sharp & Dohme Corporation (Workers)	Rahway, NJ	6/25/2014
85395	StreetLinks Lender Solutions (State/One-Stop)	Indianapolis, IN	6/25/2014
85396	Fabricast Valve, LLC (Workers)	Longview, WA	6/26/2014
85397	Accenture, LLP (Workers)	Charlotte, NC	6/26/2014
85398	Dell USA LP (Workers)	Round Rock, TX	6/26/2014
85399	Sandler & Travis Trade Advisory Services, Inc. (State/One-Stop)	Farmington Hills, MI	6/27/2014
85403	BAE Systems Aerospace & Defense Group, Inc. (State/One-Stop)	McKee, KY	6/30/2014
85403A	BAE Systems Aerospace & Defense Group, Inc. (Workers)	Annville, KY	6/30/2014
85413	Shine Electronics Company, Inc. (Company)	Long Island City, NY	7/7/2014
85419	Cinram Group Inc. (Company)	Olyphant, PA	7/14/2014
85420	Swank Inc. (State/One-Stop)	Taunton, MA	7/14/2014
85425	Intrepid Potash Inc. (State/One-Stop)	Carlsbad, NM	7/16/2014
85427	MoneyGram Payment Systems, Inc. (Workers)	Lakewood, CO	7/18/2014
85433	Wolff Fording and Company (State/One-Stop)	Richmond, VA	7/18/2014
85435	American IT Solutions (State/One-Stop)	Danbury, CT	7/22/2014
85436	PST, Inc. D/B/A Business Performance Services (Workers)	Cypress, CA	7/22/2014
85439	Qualfon Data Services Group, LLC (State/One-Stop)	Deposit, NY	7/23/2014
85441	Keystone Calumet, Inc. (Workers)	Chicago Heights, IL	7/24/2014
85442	Harman International Industries, Inc. (Workers)	Novi, MI	7/24/2014
85446	JPMorgan Chase & Co. (State/One-Stop)	Florence, SC	7/28/2014
85448	UnitedHealth One (State/One-Stop)	Lawrenceville, IL	7/29/2014
85448A	UnitedHealth One (State/One-Stop)	Indianapolis, IN	7/29/2014
85448B	UnitedHealth One (Workers)	Green Bay, WI	7/29/2014
85451	Fifth Third Mortgage Company (State/One-Stop)	Cincinnati, OH	7/29/2014
85456	Microsoft Corporation (State/One-Stop)	Redmond, WA	7/31/2014
85462	Microsoft Corporation (State/One-Stop)	Santa Monica, CA	8/5/2014
85463	Moser Baer Technologies, Inc. (Union)	Fairpoint, NY	8/5/2014
85464	Exelis Incorporated (Workers)	Roanoke, VA	8/5/2014
85466	GrafTech International Holdings, Inc. (Workers)	Emporium, PA	8/6/2014
85467	Electrolux Home Care Products, Inc. (Workers)	El Paso, TX	8/6/2014
85468	Comcast Cable (Workers)	Alpharetta, GA	8/7/2014
85470	Elsevier, Inc. (Workers)	Maryland Heights, MO	8/8/2014

APPENDIX A—LIST OF STATUTORY RECONSIDERATION OF NEGATIVE DETERMINATIONS UNDER REVERSION 2014—Continued

TA–W	Subject firm (petitioners)	Location	Date of petition filing
85477	AT&T Mobility Services LLC (State/One-Stop)	Atwater, CA	8/12/2014
85485	Stratus Technologies, Inc. (Workers)	Maynard, MA	8/15/2014
85488	Sig Sauer, Inc. (State/One-Stop)	Newington, NH	8/18/2014
85491	Citibank N.A. (Company)	Jersey City, NJ	8/18/2014
85494	Fluor-B&W Portsmouth LLC (Workers)	Piketon, OH	8/20/2014
85495	Sumitomo Electric Device Innovations USA, Inc. (State/One-Stop)	Albuquerque, NM	8/21/2014
85496	Remington Arms, Inc. (Union)	Ilion, NY	8/21/2014
85497	Invista S.a.r.l. (Workers)	Waynesboro, VA	8/22/2014
85500	J.R. Simplot Company (Workers)	Moses Lake, WA	8/25/2014
85500A	J.R. Simplot Company (Union)	Othello, WA	8/25/2014
85505	Red Shield Acquisition (Union)	Old Town, ME	8/26/2014
85508	Electrodynamics, Inc. (State/One-Stop)	Rolling Meadows, IL	8/27/2014
85513	Heartland Footwear, Inc. (Workers)	Pocahontas, AR	9/2/2014
85514	Avon Products, Inc., (State/One-Stop)	Springdale, OH	9/2/2014
85516	Bimbo Bakeries USA, Inc. (Company)	Fresno, CA	9/4/2014
85517	M&D Industries, Inc. (State/One-Stop)	Clarendon, PA	9/4/2014
85525	Amgen Inc. (Company)	Longmont, CO	9/10/2014
85527	Syncreon Technology (America), Inc. (Workers)	Allentown, PA	9/11/2014
85530	Shure Incorporated (State/One-Stop)	El Paso, TX	9/11/2014
85534	Pendleton Grain Growers, Inc. (State/One-Stop)	Hermiston, OR	9/12/2014
85534A	Pendleton Grain Growers, Inc. (State/One-Stop)	Hermiston, OR	9/12/2014
85534B	Pendleton Grain Growers, Inc. (State/One-Stop)	Hermiston, OR	9/12/2014
85534C	Pendleton Grain Growers, Inc. (State/One-Stop)	Pendleton, OR	9/12/2014
85534D	Pendleton Grain Growers, Inc. (State/One-Stop)	Pendleton, OR	9/12/2014
85534E	Pendleton Grain Growers, Inc. (State/One-Stop)	Pendleton, OR	9/12/2014
85534F	Pendleton Grain Growers, Inc. (State/One-Stop)	Pendleton, OR	9/12/2014
85534G	Pendleton Grain Growers, Inc. (State/One-Stop)	Freewater, OR	9/12/2014
85534H	Pendleton Grain Growers, Inc. (State/One-Stop)	Island City, OR	9/12/2014
85538	Centurylink, Inc. (Workers)	Seattle, WA	9/16/2014
85539	American Express Travel Related Services Company, Inc. (Workers)	Salt Lake City, UT	9/17/2014
85540	Quantum Spatial, Inc. (Workers)	Sheboygan, WI	9/17/2014
85543	Momentive Performance Materials Quartz, Inc. (Workers)	Hebron, OH	9/19/2014
85545	Rural Metro Ambulance (State/One-Stop)	Indianapolis, IN	9/22/2014
85549	Humana (State/One-Stop)	Louisville, KY	9/23/2014
85551	Harte Hanks Market Intelligence, Inc. (State/One-Stop)	San Diego, CA	9/25/2014
85555	Artic Timber, Inc. (State/One-Stop)	Cosmopolis, WA	9/25/2014
85556	Honeywell (State/One-Stop)	Tempe, AZ	9/26/2014
85559	Weatherford International LLC (Workers)	Houston, TX	9/26/2014
85562	Unimin Corporation (Workers)	Gleason, TN	9/29/2014
85571	VLOC, Inc. (Union)	Trinity, FL	10/2/2014
85573	MotivePower, Inc. (Workers)	Boise, ID	10/2/2014
85575	AMFIRE Mining Company, LLC (Union)	Portage, PA	10/3/2014
85577	British Airways, PLC (Workers)	Jamaica, NY	10/7/2014
85579	Keystone Weaving Mills, Inc. (Workers)	Lebanon, PA	10/8/2014
85581	AT&T Mobility Services LLC (State/One-Stop)	Morristown, NJ	10/9/2014
85583	Metalfab Tool & Machine, Inc. (Workers)	Mio, MI	10/9/2014
85584	Wacom Technology Corporation (State/One-Stop)	Vancouver, WA	10/9/2014
85585	AGCO (Union)	Beloit, KS	10/10/2014
85586	Delta Dental of Pennsylvania (Workers)	Mechanicsburg, PA	10/10/2014
85589	Original Chili Bowl (Company)	Tulsa, OK	10/10/2014
85594	SuperValu, Inc. (State/One-Stop)	Boise, ID	10/14/2014
85595	Quad/Graphics (Company)	Woodstock, IL	10/15/2014
85601	Pitney Bowes Inc. (State/One-Stop)	Troy, NY	10/16/2014
85603	Eighth Floor Promotions (State/One-Stop)	Celina, OH	10/17/2014
85605	GE Power Electronics, Inc. (Workers)	Galion, OH	10/20/2014
85609	RNYK LLC D.B.A. J & R Music World (State/One-Stop)	New York, NY	10/21/2014
85612	CA Technologies (State/One-Stop)	Plano, TX	10/22/2014
85613	Midair USA Inc. (State/One-Stop)	Rome, NY	10/23/2014
85615	Trane U.S. Inc. (State/One-Stop)	Tyler, TX	10/27/2014
85617	Day & Zimmermann, Inc. (Workers)	Parsons, KS	10/28/2014
85619	Oracle America, Inc. (Union)	Morrisville, NC	10/29/2014
85630	General Dynamics OTS (Pennsylvania), Inc. (State/One-Stop)	Scranton, PA	11/6/2014
85632	Intuit, Inc. (State/One-Stop)	Mountain View, CA	11/7/2014
85633	Microsoft (State/One-Stop)	Calabasas, CA	11/7/2014
85637	Cincinnati Bell Telephone Company LLC (Company)	Norwood, OH	11/10/2014
85640	Covidien LP (Workers)	Mansfield, MA	11/12/2014
85642	MetLife Group, Inc. (State/One-Stop)	Clarks Summit, PA	11/13/2014
85645	Cardinal Health (State/One-Stop)	McDonough, GA	11/14/2014
85649	Oshkosh Defense, LLC (Workers)	Oshkosh, WI	11/17/2014

APPENDIX A—LIST OF STATUTORY RECONSIDERATION OF NEGATIVE DETERMINATIONS UNDER REVERSION 2014—Continued

TA–W	Subject firm (petitioners)	Location	Date of petition filing
85656	Sprint/United Management Company (State/One-Stop)	Overland Park, KS	11/19/2014
85659	IDEV Technologies, Inc. (State/One-Stop)	Webster, TX	11/20/2014
85661	AMFIRE Mining Co. LLC (State/One-Stop)	Portage, PA	11/20/2014
85661A	Maxxim Shared Services, LLC (State/One-Stop)	Latrobe, PA	11/20/2014
85661B	AMFIRE Mining Company, LLC (State/One-Stop)	Clymer, PA	11/20/2014
85661C	AMFIRE Mining Company, LLC (State/One-Stop)	Frenchville, PA	11/20/2014
85661D	AMFIRE Mining Company, LLC (State/One-Stop)	Rockwood, PA	11/20/2014
85661E	AMFIRE Mining Company, LLC (State/One-Stop)	Indiana, PA	11/20/2014
85661F	AMFIRE Mining Company, LLC (State/One-Stop)	Hamilton, PA	11/20/2014
85661G	AMFIRE Mining Company, LLC (State/One-Stop)	Mineral Point, PA	11/20/2014
85661H	AMFIRE Mining Company, LLC (State/One-Stop)	Penn Run, PA	11/20/2014
85661I	AMFIRE Mining Company, LLC (State/One-Stop)	Indiana, PA	11/20/2014
85661J	AMFIRE Mining Company, LLC (State/One-Stop)	Homer City, PA	11/20/2014
85661K	AMFIRE Mining Company, LLC (State/One-Stop)	Mineral Point, PA	11/20/2014
85661L	AMFIRE Mining Company, LLC (State/One-Stop)	Philipsburg, PA	11/20/2014
85661M	AMFIRE Mining Company, LLC (State/One-Stop)	Clearfield, PA	11/20/2014
85661N	AMFIRE Mining Company, LLC (Union)	Homer City, PA	11/20/2014
85670	Verizon Communications (Union)	Erie, PA	11/25/2014
85672	Twin Rivers Paper LLC (State/One-Stop)	Madawaska, ME	11/26/2014
85674	Levi Strauss & Co. (Company)	Eugene, OR	11/26/2014
85676	Syncreon US (Company)	Trotwood, OH	11/28/2014
85677	Hitachi Zosen Catalyst USA, LLC (State/One-Stop)	Scottsboro, AL	11/28/2014
85693	Green Creek Wood Products LLC (State/One-Stop)	Port Angeles, WA	12/5/2014
85694	Tyco Fire Protection Products (Workers)	Westminster, MA	12/5/2014
85700	Sport Mart Inc. (Workers)	Charleston, WV	12/8/2014
85702	JP Morgan Chase & Company (Workers)	Lowell, MA	12/8/2014
85705	KeyBank, NA (State/One-Stop)	Brooklyn, OH	12/9/2014
85706	Quality Auto Electric, Inc. (Workers)	Knoxville, TN	12/10/2014
85719	Mastercraft Specialties Inc. (State/One-Stop)	Red Lion, PA	12/15/2014
85720	Xerox Commercial Solutions, LLC (State/One-Stop)	Kennett, MO	12/15/2014
85721	Workers of IBM Corporation (State/One-Stop)	San Antonio, TX	12/15/2014
85731	Sun Life Financial (U.S.) Services Company, Inc. (Company)	Wellesley Hills, MA	12/17/2014
85734	Magy Staffing (Workers)	Holland, OH	12/18/2014
85741	Maersk Agency USA Inc. (Company)	Charlotte, NC	12/22/2014
85744	Kroll Factual Data, Inc. (Workers)	Loveland, CO	12/22/2014
85747	JP Morgan Chase and Company (Workers)	Akron, OH	12/29/2014
85749	St. Thomas Medical Group (Workers)	Nashville, TN	12/31/2014
85752	Lear Corporation (Workers)	Southfield, MI	1/7/2015
85758	Oxane Materials, Inc. (State/One-Stop)	Van Buren, AR	1/12/2015
85762	Advanced Ion Beam Technology, Inc. (Workers)	Danvers, MA	1/14/2015
85765	Vencore Services and Solutions, Inc. (Union)	San Diego, CA	1/16/2015
85766	Dallas Airmotive, Inc. (Union)	Neosho, MO	1/16/2015
85769	Rural Metro Ambulance (Workers)	Salem, OR	1/20/2015
85771	Eastman Kodak Company (State/One-Stop)	Rochester, NY	1/20/2015
85772	Bank of America (State/One-Stop)	Dallas, TX	1/21/2015
85775	Laredo Petroleum, Inc. (Workers)	Farmers Branch, TX	1/21/2015
85777	Scottsdale Healthcare Hospitals (State/One-Stop)	Scottsdale, AZ	1/21/2015
85781	Asahi America, Inc. (State/One-Stop)	Lawrence, MA	1/23/2015
85782	Flight Line Products LLC (State/One-Stop)	Valencia, CA	1/23/2015
85788	Engineered Polymer Solutions (Workers)	Garland, TX	1/23/2015
85790	Corsa Coal Corporation (Workers)	Friedens, PA	1/27/2015
85791	MWI Veterinary Supply Co. (State/One-Stop)	Warsaw, NC	1/27/2015
85793	Pacific Data Images, Inc. (PDI) (Company)	Redwood City, CA	1/28/2015
85797	Revett Mining Company, Inc. (State/One-Stop)	Troy, MT	1/28/2015
85799	Comprehensive Logistics, Inc. (Company)	Lansing, MI	1/29/2015
85804	Convergys Corporation (State/One-Stop)	Jacksonville, TX	2/3/2015
85806	Premier Tech Chronos (Company)	Montgomery, AL	2/3/2015
85808	Jones Apparel US LLC (State/One-Stop)	Lawrenceburg, TN	2/4/2015
85811	Chancellors, Master, & Scholars (State/One-Stop)	West Nyack, NY	2/4/2015
85812	Deluxe 3D LLC (Workers)	Burbank, CA	2/4/2015
85813	Tyson Foods, Inc. (State/One-Stop)	Santa Teresa, NM	2/4/2015
85814	Grape Solar, Inc. (State/One-Stop)	Eugene, OR	2/5/2015
85815	Peak Oilfield Services Company (Company)	Nikiski, AK	2/5/2015
85824	HFW Ventures, LLC (State/One-Stop)	Kenai, AK	2/11/2015
85825	OxyHeal Health Group, Inc. (State/One-Stop)	Camp Lejeune, NC	2/11/2015
85829	Sony Puerto Rico, Inc. (Workers)	Guaynabo, PR	2/11/2015
85831	Carefusion (State/One-Stop)	Albuquerque, NM	2/18/2015
85832	BPRex Healthcare Brookville, Inc. (State/One-Stop)	Brookville, PA	2/18/2015
85833	Milestone Systems, Inc. (Company)	Burnsville, MN	2/18/2015

APPENDIX A—LIST OF STATUTORY RECONSIDERATION OF NEGATIVE DETERMINATIONS UNDER REVERSION 2014—Continued

TA–W	Subject firm (petitioners)	Location	Date of petition filing
85834	Mondelez International (Company)	Wilkes Barre, PA	2/18/2015
85835	S4Carlisle Publishing Services (Workers)	Dubuque, IA	2/18/2015
85838	Bethany Christian Services (State/One-Stop)	Holland, MI	2/18/2015
85840	Nestle USA (Workers)	Glendale, CA	2/19/2015
85849	Zemco Industries, Inc. (State/One-Stop)	Buffalo, NY	2/24/2015
85858	Transcend Services, Inc. (State/One-Stop)	Atlanta, GA	2/27/2015
85865	Harland Clarke Corp. (Company)	San Antonio, TX	3/6/2015
85869	ProTeam, Inc. (Workers)	Boise, ID	3/10/2015
85870	Maidenform (Workers)	Fayetteville, NC	3/11/2015
85871	Multiband Corporation (State/One-Stop)	Richmond, KY	3/11/2015
85878	MicroTelecom Systems LLC (Workers)	Uniondale, NY	3/13/2015
85880	Stewart Title Guaranty Company (State/One-Stop)	Houston, TX	3/16/2015
85881	Nabors Completion & Services Company (State/One-Stop)	Gaylord, MI	3/16/2015
85882	The Nielsen Company (US), LLC (Workers)	Shelton, CT	3/16/2015
85885	HCL America Inc. (State/One-Stop)	Cary, NC	3/19/2015
85887	Unit Drilling Company (Union)	Oklahoma City, OK	3/19/2015
85895	UNY LLC DBA General Super Plating (Union)	East Syracuse, NY	3/24/2015
85898	Siemens Energy Inc. (Workers)	Mount Vernon, OH	3/25/2015
85903	Verizon Communications (Workers)	Richardson, TX	3/26/2015
85908	PEMCO Mutual Insurance Company (Workers)	Seattle, WA	3/30/2015
85918	Interactive Data Corporation (Union)	Bedford, MA	4/1/2015
85921	Avaya, Inc. (Union)	Highlands Ranch, CO	4/2/2015
85923	Oerlikon Fairfield (State/One-Stop)	Lafayette, IN	4/6/2015
85925	Bimbo Bakeries USA, Inc. (Workers)	Fullerton, CA	4/6/2015
85936	Total Safety US (State/One-Stop)	Decatur, AL	4/10/2015
85941	CareFusion Resources, LLC (State/One-Stop)	San Diego, CA	4/15/2015
85945	International Business Machines (IBM) (Workers)	Hopewell Junction, NY	4/16/2015
85949	Asset Acceptance, LLC (State/One-Stop)	Warren, MI	4/20/2015
85965	Cathedral Art Metal Company, Inc. (State/One-Stop)	Providence, RI	4/28/2015
85966	Sirius Computer Solutions, Inc. (State/One-Stop)	San Antonio, TX	4/28/2015
85992	Verizon (State/One-Stop)	Cary, NC	5/7/2015
86003	CompuCom (State/One-Stop)	Bentonville, AR	5/11/2015
86003A	CompuCom (State/One-Stop)	Bentonville, AR	5/11/2015
86015	Bandai America Inc. (Workers)	Cypress, CA	5/15/2015
86018	Intel Corporation (Union)	Rio Rancho, NM	5/18/2015
86033	Dex Media (Union)	Bethlehem, PA	5/26/2015

APPENDIX B—LIST OF PENDING INVESTIGATIONS NOW UNDER TAARA 2015 ELIGIBILITY CRITERIA

TA–W	Subject firm (petitioners)	Location	Date of petition filing
85737	Quantum Foods (Workers)	Bolingbrook, IL	12/18/2014
85798	Windsor Foods (Workers)	Bloomsburg, PA	1/28/2015
85816	Weir Slurry Group, Inc. (Union)	Hazleton, PA	2/6/2015
85842	Sypris Tech (Workers)	Morganton, NC	2/19/2015
85852	Saint Gobain (State/One-Stop)	Fort Smith, AR	2/25/2015
85856	Norwich Pharma—Alrogen Co. (State/One-Stop)	Norwich, NY	2/27/2015
85864	Derwich Industries, Inc (State/One-Stop)	Grayling, MI	3/6/2015
85891	Fender Musical Instruments Corporation (State/One-Stop)	Corona, CA	3/20/2015
85892	Dana Holding Company (State/One-Stop)	Robinson, IL	3/23/2015
85897	American Cotton Growers LLC (State/One-Stop)	Littlefield, TX	3/24/2015
85915	Pfizer Inc. (State/One-Stop)	Groto, CT	3/31/2015
85929	IBM (State/One-Stop)	Endicott, NY	4/8/2015
85930	Teva Pharmaceuticals (Workers)	Kulztown, PA	4/8/2015
85932	Mohican Mills, Inc./Fab Industries Corp (Company)	Lincolnton, NC	4/9/2015
85937	Advanced Supply Chain International, LLC (Company)	Prudhoe Bay, AK	4/13/2015
85939	TMK—IPSCO (Workers)	Catoosa, OK	4/14/2015
85942	Halliburton (State/One-Stop)	Pocasset, OK	4/15/2015
85943	Robert Shaw Controls (Workers)	Carol Stream, IL	4/16/2015
85946	DJO Global/Exos (State/One-Stop)	Arden Hills, MN	4/17/2015
85948	Syncreon (Workers)	Allentown, PA	4/17/2015
85950	TE Connectivity (Company)	Middletown, PA	4/20/2015
85954	Baker Hughes (incl. Claremore, OK; and Hampton, AR) (Workers)	Broken Arrow, OK	4/23/2015
85956	Cameron Measurements (Workers)	Duncan, OK	4/24/2015
85957	Tatung Company of America (State/One-Stop)	Carson, CA	4/24/2015
85959	Wirerope Works Inc. (Workers)	Williamsport, PA	4/27/2015

APPENDIX B—LIST OF PENDING INVESTIGATIONS NOW UNDER TAARA 2015 ELIGIBILITY CRITERIA—Continued

TA–W	Subject firm (petitioners)	Location	Date of petition filing
85960	Hamilton Scientific (State/One-Stop)	Round Rock, TX	4/27/2015
85961	Modine Manufacturing Company (Company)	Washington, IA	4/27/2015
85964	TMK IPSCO Koppel Tubulars (Workers)	Ambridge, PA	4/27/2015
85968	Wolff Fording & Company (Workers)	Richmond, VA	4/28/2015
85975	Regulator Technologies Tulsa, LLC (Workers)	Tulsa, OK	5/1/2015
85976	Bonney Forge (Workers)	Mount Union, PA	5/1/2015
85977	Sanquine Gas Exploration LLC (State/One-Stop)	Tulsa, OK	5/4/2015
85978	Simpson Lumber LLC (Union)	Shelton, WA	5/4/2015
85981	Stein Steel Mill Services, Inc. (Union)	Granite City, IL	5/5/2015
85982	Bosch Securities Inc. (Union)	Lancaster, PA	5/5/2015
85983	MegaDiamond (Workers)	Provo, UT	5/5/2015
85985	New Wave Surgical/Covidien (Company)	Pompano Bay, FL	5/5/2015
85988	Nextit (State/One-Stop)	Spokane, WA	5/6/2015
85989	Milliken & Company (Company)	Greenville, SC	5/6/2015
85990	Maxim Integrated (State/One-Stop)	Hillsboro, OR	5/6/2015
85991	Caterpillar, Inc. (State/One-Stop)	Decatur, IL	5/7/2015
85993	TMK–IPSCO Tubulars Kentucky Inc (Union)	Wilder, KY	5/7/2015
85994	Superior Industries International, Inc. (Company)	Van Nuys, CA	5/7/2015
85995	Seacon Brantner & Associates (Company)	El Cajon, CA	5/7/2015
85996	Willbanks Metals, Inc. fka First Process Steel (State/One-Stop)	Tulsa, OK	5/7/2015
85998	Baker Hughes Oilfield Operations, Inc. (State/One-Stop)	Hampton, AR	5/8/2015
85999	Carlson Craft (State/One-Stop)	North Mankato, MN	5/8/2015
86000	Cudd Energy Services (State/One-Stop)	Seminole, OK	5/8/2015
86001	Boeing Commercial Aircraft (Union)	Tukwila, WA	5/11/2015
86002	Cameron (State/One-Stop)	Little Rock, AR	5/11/2015
86004	Cooper Power Systems (State/One-Stop)	Fayetteville, AR	5/11/2015
86005	DCP Midstream (State/One-Stop)	Tulsa, OK	5/11/2015
86007	Goldwin America, Inc a Subsidiary of Goldwin Inc. (State/One-Stop)	Manhattan Beach, CA	5/11/2015
86008	John Deere Des Moines Works (State/One-Stop)	Ankeny, IA	5/11/2015
86009	DestaDrilling (Workers)	Odessa, TX	5/12/2015
86010	Convergys Corporation Pharr Texas (Workers)	Pharr, TX	5/13/2015
86011	Goodman Networks, Inc. (Company)	Plano including remote workers, TX.	5/13/2015
86013	Samson Resources (Workers)	Tulsa, OK	5/14/2015
86016	Rexnord Gear Products Division (State/One-Stop)	Milwaukee, WI	5/15/2015
86017	TMK—IPSCO (Company)	Houston, TX	5/15/2015
86020	Harsco Air Exchangers (State/One-Stop)	Catoosa, OK	5/20/2015
86021	The Shredder Company, LLC. (Workers)	Canutillo, TX	5/20/2015
86022	Oil States Energy Services (Workers)	Cannonsburg, PA	5/20/2015
86023	Team Oil Tools (State/One-Stop)	Tulsa, OK	5/20/2015
86024	Chart Industries (State/One-Stop)	Owatonna, MN	5/20/2015
86025	Actavis, Inc.—(Watson Laboratories, Inc.) (State/One-Stop)	Corona, CA	5/21/2015
86026	Gardner-Denver (Workers)	Tulsa, OK	5/21/2015
86027	Pittsburgh Corning Corporation (Union)	Port Allegany, PA	5/22/2015
86028	Transicoil (Company)	Collegeville, PA	5/22/2015
86029	Cadmus Communications, a Cenveo Company (Workers)	Lancaster, PA	5/22/2015
86030	Goodman Networks, Inc. (Workers)	Plano, TX	5/26/2015
86031	Oil State Industries International (State/One-Stop)	Tulsa, OK	5/26/2015
86032	Tefelex Medical, Inc. (Company)	Asheboro, NC	5/26/2015
86034	Technicolor Creative Services (Workers)	Hollywood, CA	5/26/2015
86035	Sykes Home Powered by Alpine Access (Workers)	Denver, CO	5/26/2015
86036	Flowers Foods, Inc. (State/One-Stop)	Waterloo, IA	5/26/2015
86037	Craftwood, Inc. (Workers)	High Point, NC	5/27/2015
86038	Pearson (Workers)	Old Tappan, NJ	5/28/2015
86039	Arcelormittal—Georgetown (Union)	Georgetown, SC	5/28/2015
86040	ATOS IT Solutions and Services, Inc. (Company)	Mason, OH	5/29/2015
86041	LA Darling Company (Workers)	Piggott, AR	5/29/2015
86042	S&R Equipment Co (State/One-Stop)	Austin, TX	5/29/2015
86043	UBM, LLC (State/One-Stop)	Manhasset, NY	5/29/2015
86044	Interfor (Union)	Tacoma, WA	5/29/2015
86045	Riley Gear Corporation (Union)	North Tonawanda, NY	5/29/2015
86046	Aercap (State/One-Stop)	Los Angeles, CA	6/1/2015
86047	Republic Steel (Union)	Gary, IN	6/1/2015
86048	Spirit Aerosystem (Workers)	Tulsa, OK	6/1/2015
86049	Green Diamond Company/California Redwood Company (State/One-Stop).	Eureka, CA	6/1/2015
86050	Bank Of America (Workers)	Simi Valley, CA	6/1/2015
86051	Archer Pressure Pumping, LLC (Workers)	Union City, OK	6/1/2015
86052	Southwestern Wire Cloth (Workers)	Broken Arrow, OK	6/1/2015
86053	Medco/Express Scripts (State/One-Stop)	Jersey City, NJ	6/2/2015

APPENDIX B—LIST OF PENDING INVESTIGATIONS NOW UNDER TAARA 2015 ELIGIBILITY CRITERIA—Continued

TA–W	Subject firm (petitioners)	Location	Date of petition filing
86055	Aztec Well Servicing Companies (Company)	Aztec, NM	6/2/2015
86056	Kapstone Paper and Packaging Inc. (Union)	Longview, WA	6/2/2015
86057	Fairmount Santrol (Brewer Facility) (State/One-Stop)	Perryville, MO	6/3/2015
86058	Merkle Inc. (State/One-Stop)	Montvale, NJ	6/3/2015
86059	OGCI—Petro Skills (State/One-Stop)	Tulsa, OK	6/3/2015
86060	Worthington Industries (State/One-Stop)	Florence, SC	6/4/2015
86061	ArcelorMittal Ferndale, Inc. (Company)	Ferndale, MI	6/4/2015
86062	Chromalloy Southwest (Company)	Calexico, CA	6/4/2015
86063	Heritage Home (Workers)	Saltillo, MS	6/4/2015
86064	Texas Instruments Incorporated (Company)	Stafford, TX	6/4/2015
86065	Cliffs Natural Resources (State/One-Stop)	Ishpeming, MI	6/5/2015
86066	Contec LLC (Workers)	Brownsville, TX	6/5/2015
86067	Guardian Life Insurance Company (Company)	Appleton, WA	6/5/2015
86068	Rockwell Collins Inc. (Workers)	Calexico, CA	6/5/2015
86069	Schlumberger (State/One-Stop)	Kellyville, OK	6/5/2015
86070	Interplex Tech Group (Workers)	North Haven, CT	6/8/2015
86071	INVISTA (Company)	Athens, GA	6/8/2015
86072	Conoco-Phillips, IT Dept. (State/One-Stop)	Bartlesville, OK	6/8/2015
86073	Norwich Aero Products (Esterline) (State/One-Stop)	Norwich, NY	6/8/2015
86074	W.W. Grainger (State/One-Stop)	Lincolnshire, IL	6/8/2015
86075	Epic Technologies, LLC (Company)	Johnson City, TN	6/8/2015
86076	Omnicare Inc. (Workers)	Dublin, OH	6/9/2015
86077	HARMAN (Company)	Northridge, CA	6/9/2015
86078	Best Well Services, LLC. (State/One-Stop)	Guthrie, OK	6/9/2015
86079	Airboss Defense Inc. (Company)	Milton, VT	6/9/2015
86080	Sercel GRC (State/One-Stop)	Tulsa, OK	6/10/2015
86081	Milco Industries, Inc. (Company)	Bloomsburg, PA	6/10/2015
86082	AA Gear and Manufacturing (State/One-Stop)	Howell, MI	6/10/2015
86083	Magnetation (State/One-Stop)	Grand Rapids, MN	6/10/2015
86084	DexMedia (Workers)	Los Alamitos, CA	6/10/2015
86085	Research in Motion (Blackberry) (State/One-Stop)	Milford, CT	6/11/2015
86086	Mesabi Nugget/Steel Dynamics (State/One-Stop)	Chisholm/Hoyt Lakes, MN	6/11/2015
86087	Horton Automatics, Sheet Metal Technicians, hourly plant employees (Company).	Corpus Christi, TX	6/11/2015
86088	Breg, Inc. (State/One-Stop)	Grand Prairie, TX	6/11/2015
86089	Huntington Alloys Corporation (Union)	Huntington, WV	6/11/2015
86090	CoorsTek (State/One-Stop)	Tulsa, OK	6/12/2015
86091	Frontier Airlines (State/One-Stop)	Denver, CO	6/15/2015
86092	National Electronic Warranty/Asurion (State/One-Stop)	Sterling, VA	6/15/2015
86093	EarthLink (State/One-Stop)	Rochester, NY	6/16/2015
86094	Optical Disc Solutions (Workers)	Richmond, IN	6/16/2015
86095	Essentra (Union)	Evansville, IN	6/16/2015
86096	Dow Electronic Materials—Metal Organics incl. Kelly Srvcs & US Security (Workers).	North Andover, MA	6/16/2015
86097	Heritage Glass LLC (Workers)	Kingsport, TN	6/17/2015
86098	Mattel, Inc. (State/One-Stop)	El Segundo, CA	6/17/2015
86099	Mohawk Industries (Company)	Landrum, SC	6/17/2015
86100	Novartis/GSK Consumer Health Care (Workers)	Lincoln, NE	6/17/2015
86101	Paragon Store Fixtures (Company)	Big Lake, MN	6/17/2015
86102	Vonage America (Workers)	Holmdel, NJ	6/17/2015
86103	Wilbros (State/One-Stop)	Tulsa, OK	6/17/2015
86104	Northwest Pipe Company (State/One-Stop)	Atchison, KS	6/18/2015
86105	Safran Labinal Power Systems (Company)	Salisbury, MD	6/18/2015
86106	Tucker Energy Services/McAlester OK (State/One-Stop)	Tulsa, OK	6/18/2015
86107	Dex Media (State/One-Stop)	DFW Airport, TX	6/19/2015
86108	SOL INC (Workers)	Palm City, FL	6/19/2015
86109	Mammoth Webco (State/One-Stop)	Springfield, MO	6/19/2015
86110	Allen Logging Co, Inc. (State/One-Stop)	Forks, WA	6/19/2015
86111	Seattle-Snohomish Sawmill Co. Inc. (State/One-Stop)	Snohomish, WA	6/19/2015
86112	Avantor Performance Materials (Workers)	Paris, KY	6/22/2015
86113	Soo Tractor LLC (formerly Radius Steel) (State/One-Stop)	Sioux City, IA	6/22/2015
86114	Regal Beloit America, Inc. (Company)	West Plains, MO	6/22/2015
86115	GGS Information Services (Company)	Erie, PA	6/22/2015
86116	Quad Graphics (State/One-Stop)	Portland, OR	6/23/2015
86117	Conoco Phillips (State/One-Stop)	Farmington, NM	6/23/2015
86118	Producers Assistants Corp (State/One-Stop)	Farmington, NM	6/23/2015
86119	Frac Master LLC (Workers)	Farmington, NM	6/23/2015
86120	Avery Dennison (Company)	Greensboro, NC	6/23/2015
86121	Sandvik Coromant (Workers)	Pontiac, MI	6/23/2015
86122	Hospira (Company)	Clayton, NC	6/23/2015

APPENDIX B—LIST OF PENDING INVESTIGATIONS NOW UNDER TAARA 2015 ELIGIBILITY CRITERIA—Continued

TA–W	Subject firm (petitioners)	Location	Date of petition filing
86123	Bombardier Transportation (Workers)	Pittsburgh, PA	6/23/2015
86124	E. H. Wachs/ITW (State/One-Stop)	Lincolnshire, IL	6/24/2015
86125	Verizon Business (State/One-Stop)	Tulsa, OK	6/24/2015
86126	Solid State Advanced Controls (Company)	Baldwinsville, NY	6/25/2015
86127	Johnson Metall, Inc. (Workers)	Lorain, OH	6/25/2015
86128	QBE First (Workers)	Moon Township, PA	6/25/2015
86129	Frog, Switch, and MFG CO (Workers)	Carlisle, PA	6/25/2015
86130	Vera Bradley Designs (Company)	New Haven, IN	6/25/2015
86131	WPX Energy Services Company , LLC (State/One-Stop)	Tulsa, OH	6/25/2015
86132	Getinge Sourcing, LLC (Company)	Rochester, NY	6/26/2015
86133	Capital Group Companies Global, Inc. (Workers)	San Antonio, TX	6/26/2015
86134	ESCI/Thorpe Inc. (State/One-Stop)	Broken Arrow, OK	6/26/2015
86135	Harrington Machine & Tool Co Inc (Company)	Franklin, PA	6/29/2015
86136	Verizon (Workers)	Lake Mary, FL	6/29/2015
86137	Dex Media (Union)	Williamsville, NY	6/29/2015
86138	Verizon (Workers)	Richard, TX	6/29/2015
86139	JMC Steel Group (Union)	Whertland, PA	6/29/2015

DATES: This Notice is effective immediately/June 29, 2015.

For Further Information or Questions on Statutory Reconsiderations for Trade Adjustment Assistance: Please contact the 1–877–US2–JOBS (TTY) 1–877–889–5627 (both lines are Toll free) or via the Internet at *www.doleta.gov/tradeact.*

Portia Wu,

Assistant Secretary for Employment and Training.

[FR Doc. 2015–20234 Filed 8–14–15; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Cadmium in Construction Standard

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Cadmium in Construction Standard,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 16, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=20201505-1218-008* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Cadmium in Construction Standard information collection requirements codified in regulations 29 CFR 1926.1127. The major information collection requirements in the Standard include: Conducting worker exposure monitoring; notifying workers of their cadmium exposures; implementing a written compliance program; implementing medical surveillance of workers; providing examining physicians with specific information; ensuring workers receive a copy of their medical surveillance results; maintaining workers' exposure monitoring and medical surveillance records for specific periods; and providing access to these records by the worker who is the subject of the records, the worker's representative, and other designated parties. Occupational Safety and Health Act sections 2(b)(9), 6, and 8(c) authorize this information collection. *See* 29 U.S.C. 651(b)(9), 655, and 657(c).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0186.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on August 31, 2015. The DOL seeks to extend PRA authorization for this

information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 21, 2015 (80 FR 29346).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0186. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OSHA.

Title of Collection: Cadmium in Construction Standard.

OMB Control Number: 1218–0186.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 10,000.

Total Estimated Number of Responses: 258,249.

Total Estimated Annual Time Burden: 33,720 hours.

Total Estimated Annual Other Costs Burden: $2,082,199.

Dated: August 11, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–20151 Filed 8–14–15; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Proposed Extension of Existing Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Claim for Medical Reimbursement (OWCP–915). A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before October 16, 2015.

ADDRESSES: Ms. Yoon Ferguson, U.S. Department of Labor, 200 Constitution Ave. NW., Room S–3323, Washington, DC 20210, telephone/FAX (202) 354–9647, Email *ferguson.yoon@dol.gov.* Please use only one method of transmission for comments (mail or Email).

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Workers' Compensation Programs (OWCP) is the agency responsible for administration of the Federal Employees' Compensation Act (FECA), 5 U.S.C. 8101 *et seq.,* the Black Lung Benefits Act (BLBA), 30 U.S.C. 901 *et seq.,* and the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384 *et seq.* All three statutes require OWCP to pay for covered medical treatment that is provided to beneficiaries, and also to reimburse beneficiaries for any out-of-pocket covered medical expenses they have paid. Form OWCP–915, Claim for Medical Reimbursement, is used for this purpose and collects the necessary beneficiary and medical provider data in a standard format. Regulations implementing the FECA, BLBA and EEOICPA programs require the collection of information that is needed to determine if reimbursement claims submitted by beneficiaries can be paid. (20 CFR 10.802, 30.702, 725.701 and 725.705). This information collection is currently approved for use through January 31, 2016.

II. Review Focus

The Department of Labor is particularly interested in comments which:

* Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

* evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* enhance the quality, utility and clarity of the information to be collected; and

* minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

The Department of Labor seeks the approval of the extension of this currently approved information collection in order to carry out its responsibility to provide payment for certain covered medical services to injured employees who are covered under the Acts.

Type of Review: Extension.

Agency: Office of Workers' Compensation Programs.

Title: Claim for Medical Reimbursement.

OMB Number: 1240–0007.

Agency Number: OWCP–915.

Affected Public: Individual or Households; Business or other-for-profit; Not-for-profit institutions.

Total Respondents: 10,632.

Total Responses: 38,480.

Time per Response: 10 minutes.

Estimated Total Burden Hours: 6,388.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $68,879.

Comments submitted in response to this notice will be summarized and/or

included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: August 11, 2015.

Yoon Ferguson,

Agency Clearance Officer, Office of Workers' Compensation Programs, U.S. Department of Labor.

[FR Doc. 2015–20152 Filed 8–14–15; 8:45 am]

BILLING CODE 4510–CR–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Radiation Protection and Nuclear Materials; Notice of Meeting

The ACRS Subcommittee on Radiation Protection and Nuclear Materials will hold a meeting on August 19, 2015, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland 20852.

The meeting will be open to public attendance with the exception of portions that may be closed to protect information that is propriety pursuant to 5 U.S.C. 552b(c)(4). The agenda for the subject meeting shall be as follows:

Wednesday, August 19, 2015—8:30 a.m. Until 5:00 p.m.

The Subcommittee will review and discuss the SHINE Medical Technologies (SHINE) construction permit application for Mo99 medical radioisotope production facility under 10 CFR part 50 and the staff's Safety Evaluation Report, Chapters 1, 2, 4, 5, 6a, 7, 8. The Subcommittee will hear presentations by and hold discussions with SHINE, the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Maitri Banerjee (Telephone: 301–415–6973 or Email: *Maitri.Banerjee@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be Emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 1, 2014 (79 FR 59307–59308).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North Building, 11555 Rockville Pike, Rockville, Maryland 20152. After registering with Security, please contact Mr. Theron Brown (Telephone: 240–888–9835) to be escorted to the meeting room.

Dated: August 6, 2015.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2015–20313 Filed 8–14–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0001]

Sunshine Act Meeting Notice

DATE: August 17, 24, 31, September 7, 14, 21, 2015.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of August 17, 2015

There are no meetings scheduled for the week of August 17, 2015.

Week of August 24, 2015—Tentative

There are no meetings scheduled for the week of August 24, 2015.

Week of August 31, 2015—Tentative

There are no meetings scheduled for the week of August 31, 2015.

Week of September 7, 2015—Tentative

Tuesday, September 8, 2015

9:30 a.m. Briefing on Project AIM 2020 (Public Meeting) (Contact: Karen Fitch: 301–415–7358)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, September 10, 2015

9:30 a.m. Briefing on NRC International Activities (Closed—Ex. 1 & 9)

Week of September 14, 2015—Tentative

There are no meetings scheduled for the week of September 14, 2015.

Week of September 21, 2015

Thursday, September 24, 2015

9:30 a.m. Strategic Programmatic Overview of the New Reactors Business Line (Public Meeting) (Contact: Donna Williams: 301–415–1322)

* * * * *

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Glenn Ellmers at 301–415–0442 or via email at *Glenn.Ellmers@nrc.gov.*

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

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, NRC Disability Program Manager, at 301–287–0727, 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.

* * * * *

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 email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: August 13, 2015.

Glenn Ellmers,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2015–20361 Filed 8–13–15; 4:15 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75662; File No. SR–NYSEARCA–2015–67]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Holdings By the iShares Interest Rate Hedged Corporate Bond ETF and iShares Interest Rate Hedged High Yield Bond ETF

August 11, 2015.

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 August 3, 2015, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the 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 reflect a change to the holdings to be implemented by the iShares Interest Rate Hedged Corporate Bond ETF and iShares Interest Rate Hedged High Yield Bond ETF relating to the use of interest rate futures contracts, and interest rate swaps. The text of the proposed rule change is available on the Exchange's Web site 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 Commission has approved a proposal to list and trade on the Exchange shares (''Shares'') of the iShares Interest Rate Hedged Corporate Bond ETF and iShares Interest Rate Hedged High Yield Bond ETF (each a ''Fund'' and, together, the ''Funds'') under NYSE Arca Equities Rule 8.600,[4] which governs the listing and trading of Managed Fund Shares.[5]

The Shares of the Funds are offered by iShares U.S. ETF Trust (the ''Trust'').[6] The Trust is registered with the Commission as an open-end management investment company. BlackRock Fund Advisors (''BFA'') serves as the investment adviser to the Funds (the ''Adviser''). BFA is an indirect wholly-owned subsidiary of BlackRock, Inc. BlackRock Investments, LLC is the principal underwriter and distributor of the Funds' Shares. State Street Bank and Trust Company serves as administrator, custodian and transfer agent for the Funds. The Funds' Shares are currently listed and traded on the Exchange under NYSE Arca Equities Rule 8.600.

The Exchange proposes to revise the representations made in the Prior Release regarding the Funds' investments to accommodate use of interest rate futures contracts [7] and interest rate swaps by the Funds, as described below, consistent with the use of such financial instruments permitted for other funds of the Trust previously approved by the Commission for Exchange listing and trading.[8]

iShares Interest Rate Hedged Corporate Bond ETF

As described in the Prior Release, according to the Corporate Bond Registration Statement, the Fund seeks to mitigate the interest rate risk of a portfolio composed of U.S. dollar-denominated, investment grade corporate bonds. The Fund seeks to achieve its investment objective by investing, under normal circumstances, at least 80% of its net assets in U.S. dollar-denominated investment grade bonds, in one or more investment companies (exchange-traded and non-exchange-traded funds) that principally invest in investment-grade bonds, in U.S. Treasury securities (or cash equivalents), and by taking short positions in U.S. Treasury futures and other interest rate futures contracts.

The Exchange proposes to amend this statement to provide that, going forward, the Fund will seek to achieve its investment objective by investing, under normal circumstances, at least 80% of its net assets in U.S. dollar-denominated investment grade bonds, in one or more investment companies (exchange-traded and non-exchange-traded funds) that principally invest in investment-grade bonds, in U.S. Treasury securities (or cash

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release Nos. 71778 (March 24, 2014), 79 FR 17585 (March 28, 2014 (SR–NYSEArca–2014–23) (Notice of Filing of Proposed Rule Change to List and Trade Shares of the iShares Interest Rate Hedged Corporate Bond ETF and iShares Interest Rate Hedged High Yield Bond ETF under NYSE Arca Equities Rule 8.600) (''Prior Notice''); 72138 (May 9, 2014), 79 FR 27958 (May 15, 2014) (SR–NYSEArca–2014–23) (order approving listing and trading on the Exchange of Shares of the iShares Interest Rate Hedged Corporate Bond ETF and iShares Interest Rate Hedged High Yield Bond ETF under NYSE Arca Equities Rule 8.600) (''Prior Order'' and, together with the Prior Notice, the ''Prior Release'').

[5] A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act'') organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Equities Rule 5.2(j)(3), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

[6] The Trust is registered under the 1940 Act. On August 22, 2013, the Trust filed with the Commission post-effective amendments on Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a) and under the 1940 Act relating to the iShares Interest Rate Hedged Corporate Bond ETF (the ''Corporate Bond Registration Statement'') and the iShares Interest Rate Hedged High Yield Bond ETF (the ''High Yield Registration Statement'' and together with the Corporate Bond Registration Statement, the ''Registration Statements'') (File Nos. 333–179904 and 811–22649). In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 29571 (File No. 812–13601) (''Exemptive Order'').

[7] As described in the Prior Release, both Funds may use U.S. Treasury futures contracts to mitigate interest rate risk. In this proposed rule change, the Exchange proposes, among other things, to accommodate use by the Funds of other interest rate futures to mitigate interest rate risk.

[8] *See* Securities Exchange Act Release No. 74058 (January 15, 2015), 80 FR 3294 (January 22, 2015) (SR–NYSEArca–2014–114), (order approving listing and trading on the Exchange of shares of the iShares Interest Rate Hedged 0–5 Year High Yield Bond ETF, iShares Interest Rate Hedged 10+ Year Credit Bond ETF, and the iShares Interest Rate Hedged Emerging Markets Bond ETF under NYSE Arca Equities Rule 8.600).

equivalents), and by taking short positions in U.S. Treasury futures, other interest rate futures contracts, and interest rate swaps.[9]

The Prior Release also stated that, according to the Corporate Bond Registration Statement, the Fund initially intends to invest a substantial portion of its assets in the iShares iBoxx $ Investment Grade Corporate Bond ETF (the ''Underlying Corporate Bond Fund''). The Fund attempts to mitigate interest rate risk primarily through the use of U.S. Treasury futures contracts.

The Exchange proposes to amend the statement in the last sentence of the preceding paragraph to state that, going forward, the Fund will attempt to mitigate interest rate risk primarily through the use of U.S. Treasury futures contracts, interest rate futures, and interest rate swaps.

The Prior Release stated that BFA will utilize a model-based proprietary investment process to assemble an investment portfolio comprised of (i) long positions in the Underlying Corporate Bond Fund, (ii) long positions in U.S. dollar-denominated investment-grade corporate bonds, (iii) long positions in U.S. Treasury securities and (iv) short positions in U.S. Treasury futures and other interest rate futures contracts.

The Exchange proposes to amend the statement in item (iv) of the preceding paragraph to provide that, going forward, the investment portfolio referred to in the preceding paragraph may be comprised of short positions in U.S. Treasury futures, other interest rate futures contracts, and interest rate swaps.

iShares Interest Rate Hedged High Yield Bond ETF

According to the High Yield Registration Statement, the Fund seeks to mitigate the interest rate risk of a portfolio composed of U.S. dollar-denominated, high yield corporate bonds. The Fund seeks to achieve its investment objective by investing, under normal circumstances, at least 80% of its net assets in U.S. dollar-denominated high yield corporate bonds, in one or more investment companies (exchange-traded and non-exchange-traded funds) that principally invest in high yield bonds, in U.S. Treasury securities (or cash equivalents), and by taking short positions in U.S. Treasury futures and other interest rate futures contracts.

The Exchange proposes to amend this statement to provide that, going forward, the Fund will seek to achieve its investment objective by investing, under normal circumstances, at least 80% of its net assets in U.S. dollar-denominated high yield corporate bonds, in one or more investment companies (exchange-traded and non-exchange-traded funds) that principally invest in high yield bonds, in U.S. Treasury securities (or cash equivalents), and by taking short positions in U.S. Treasury futures, other interest rate futures contracts, and interest rate swaps.[10]

The Prior Release also stated that, according to the High Yield Registration Statement, the Fund initially intends to invest a substantial portion of its assets in the iShares iBoxx $ High Yield Corporate Bond ETF. The Fund will attempt to mitigate interest rate risk primarily through the use of U.S. Treasury futures contracts.

The Exchange proposes to amend the last sentence of the preceding paragraph to provide that, going forward, the Fund will attempt to mitigate interest rate risk primarily through the use of U.S. Treasury futures contracts, other interest rate futures contracts, and interest rate swaps.

The Prior Release stated that BFA will utilize a model-based proprietary investment process to assemble an investment portfolio comprised of (i) long positions in the Underlying High Yield Bond Fund, (ii) long positions in U.S. dollar-denominated high yield corporate bonds, (iii) long positions in U.S. Treasury securities and (iv) short positions in U.S. Treasury futures and other interest rate futures contracts.

The Exchange proposes to amend the statement in item (iv) of the preceding paragraph to provide that, going forward, the investment portfolio referred to in the preceding paragraph may be comprised of short positions in U.S. Treasury futures, other interest rate futures contracts, and interest rate swaps.

The section ''Determination of Net Asset Value'' in the Prior Release did not include reference to swaps. The Exchange proposes to state that swaps and other derivatives will generally be valued based upon quotations from market makers or by a pricing service in accordance with valuation procedures approved by Trust's Board of Directors.

On a daily basis, each of the Funds will disclose for each portfolio security or other financial instrument the following information on the Funds' Web site: Ticker symbol, if any; CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap); the identity of the security or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value or number of shares, contracts or units); maturity date, if any; coupon rate, if any; market value of the holding; and the percentage weighting of the holding in the portfolio. The Web site information will be publicly available at no charge.

The Adviser represents that the proposed changes relating to the Funds' holdings in interest rate swaps, as described above, are consistent with the Fund's investment objective, and will further assist the Adviser to achieve such investment objective. In addition, such proposed changes are consistent with the use of swaps permitted for shares of other funds of the Trust previously approved by the Commission for Exchange listing and trading.[11]

Except for the changes noted above, all other representations made in the Prior Release remain unchanged. The Funds will continue to comply with all initial and continued listing requirements under NYSE Arca Equities Rule 8.600.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under section 6(b)(5)[12] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.600. The Funds will invest only in futures contracts that are traded on an exchange that is a member of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Swaps will be centrally cleared. All derivatives held by the Funds will be collateralized.

The proposed rule change is designed to promote just and equitable principles

[9] The Funds will invest only in futures contracts that are traded on an exchange that is a member of the Intermarket Surveillance Group (''ISG'') or with which the Exchange has in place a comprehensive surveillance sharing agreement. Swaps will be centrally cleared. All derivatives held by the Funds will be collateralized.

[10] *See* note 9, *supra.*

[11] *See* note 8, *supra.*

[12] 15 U.S.C. 78f(b)(5).

of trade and to protect investors and the public interest. The Adviser represents that the proposed changes relating to the Funds' holdings in U.S. Treasury futures, other interest rate futures contracts, and interest rate swaps, as described above, are consistent with each Fund's investment objective, and will further assist the Adviser to achieve each such investment objective. In addition, such proposed changes are consistent with the use of U.S. Treasury futures, other interest rate futures contracts, and interest rate swaps permitted for shares of other funds of the Trust previously approved by the Commission for Exchange listing and trading.[13]

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. The Adviser represents that the proposed changes relating to the Funds' holdings in U.S. Treasury futures, other interest rate futures contracts, and interest rate swaps, as described above, are consistent with each Fund's investment objective, and will further assist the Adviser to achieve each such investment objective. In addition, such proposed changes are consistent with the use of U.S. Treasury futures, other interest rate futures contracts, and interest rate swaps permitted for shares of other funds of the Trust previously approved by the Commission for Exchange listing and trading.[14] Such changes would enhance the ability of the Funds to mitigate interest rate risk. The Funds will invest only in futures contracts that are traded on an exchange that is a member of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Swaps will be centrally cleared. All derivatives held by the Funds will be collateralized. The Adviser represents that the investment objective of each Fund has not changed. Except for the changes noted above, all other representations made in the Prior Release remain unchanged. The Funds will continue to comply with all initial and continued listing requirements under NYSE Arca Equities Rule 8.600.

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 believes the proposed rule change, in permitting each Fund to utilize other interest rate futures and interest rate swaps as part of its portfolio to achieve its investment objective, will enhance competition among issues of Managed Fund Shares that invest principally in fixed income securities.

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 Exchange has filed the proposed rule change pursuant to section 19(b)(3)(A)(iii) of the Act[15] and Rule 19b–4(f)(6) thereunder.[16] Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) 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 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–NYSEArca–2015–67 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–NYSEArca–2015–67. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2015–67 and should be submitted on or before September 8, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Brent J. Fields,

Secretary.

[FR Doc. 2015–20158 Filed 8–14–15; 8:45 am]

BILLING CODE 8011–01–P

[13] *See* note 8, *supra.*

[14] *See* note 8, *supra.*

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31745; 812–14495]

Victory NextShares Trust, et al.; Notice of Application

August 11, 2015.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections

2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act.

APPLICANTS: Victory NextShares Trust (the ''Trust''), Victory Capital Management Inc. (the ''Adviser'') and Victory Capital Advisers, Inc. (the ''Distributor'').

SUMMARY: *Summary of Application:* Applicants request an order (''Order'') that permits: (a) Actively managed series of certain open-end management investment companies to issue shares (''Shares'') redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Shares to occur at the next-determined net asset value plus or minus a market-determined premium or discount that may vary during the trading day; (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days from the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares; and (f) certain series to create and redeem Shares in kind in a master-feeder structure. The Order would incorporate by reference terms and conditions of a previous order granting the same relief sought by applicants, as that order may be amended from time to time (''Reference Order'').[1]

DATES: *Filing Date:* The application was filed on June 25, 2015.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on September 8, 2015, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: The Commission: Brent J. Fields, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: Victory NextShares Trust, Victory Capital Management Inc., and Victory Capital Advisers, Inc., 4900 Tiedeman Rd., Brooklyn, OH 44144.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus, Paralegal Specialist, or Dalia Osman Blass, Assistant Chief Counsel, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants

1. The Trust will be registered as an open-end management investment company under the Act and is a statutory business trust organized under the laws of Delaware. Applicants seek relief with respect to nine Funds (as defined below, and those Funds, the ''Initial Funds''). The portfolio positions of each Fund will consist of securities and other assets selected and managed by its Adviser or Subadviser (as defined below) to pursue the Fund's investment objective.

2. The Adviser, a New York corporation, will be the investment adviser to the Initial Funds. An Adviser (as defined below) will serve as investment adviser to each Fund. The Adviser is, and any other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). The Adviser and the Trust may retain one or more subadvisers (each a ''Subadviser'') to manage the portfolios of the Funds. Any Subadviser will be registered, or not subject to registration, under the Advisers Act.

3. The Distributor is a Delaware corporation and a broker-dealer registered under the Securities Exchange Act of 1934 and will act as the principal underwriter of Shares of the Funds. Applicants request that the requested relief apply to any distributor of Shares, whether affiliated or unaffiliated with the Adviser (included in the term ''Distributor''). Any Distributor will comply with the terms and conditions of the Order.

Applicants' Requested Exemptive Relief

4. Applicants seek the requested Order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c-1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act. The requested Order would permit applicants to offer exchange-traded managed funds. Because the relief requested is the same as the relief granted by the Commission under the Reference Order and because the Adviser has entered into, or anticipates entering into, a licensing agreement with Eaton Vance Management, or an affiliate thereof in order to offer exchange-traded managed funds,[2] the Order would incorporate by reference the terms and conditions of the Reference Order.

5. Applicants request that the Order apply to the Initial Funds and to any other existing or future open-end management investment company or series thereof that: (a) Is advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser (any such entity included in the term ''Adviser''); and (b) operates as an exchange-traded managed fund as described in the Reference Order; and (c) complies with the terms and conditions of the Order and of the Reference Order, which is incorporated by reference herein (each such company or series and Initial Fund, a ''Fund'').[3]

6. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the

[1] Eaton Vance Management, *et al.,* Investment Company Act Rel. Nos. 31333 (Nov. 6, 2014) (notice) and 31361 (Dec. 2, 2014) (order).

[2] Eaton Vance Management has obtained patents with respect to certain aspects of the Funds' method of operation as exchange-traded managed funds.

[3] All entities that currently intend to rely on the Order are named as applicants. Any other entity that relies on the Order in the future will comply with the terms and conditions of the Order and of the Reference Order, which is incorporated by reference herein.

transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

7. Applicants submit that for the reasons stated in the Reference Order: (1) With respect to the relief requested pursuant to section 6(c) of the Act, the relief is appropriate, in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act; (2) with respect to the relief request pursuant to section 17(b) of the Act, the proposed transactions are reasonable and fair and do not involve overreaching on the part of any person concerned, are consistent with the policies of each registered investment company concerned and consistent with the general purposes of the Act; and (3) with respect to the relief requested pursuant to section 12(d)(1)(J) of the Act, the relief is consistent with the public interest and the protection of investors.

By the Division of Investment Management, pursuant to delegated authority.

Robert W. Errett

Deputy Secretary.

[FR Doc. 2015–20160 Filed 8–14–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75659; File No. SR–NYSE–2015–27]

Self-Regulatory Organizations; New York Stock Exchange LLC; Designation of a Longer Period for Commission Action on a Proposed Rule Change Amending the Eighth Amended and Restated Operating Agreement of the Exchange To Establish a Regulatory Oversight Committee as a Committee of the Board of Directors of the Exchange and Make Certain Conforming Amendments to Exchange Rules

August 11, 2015.

On June 12, 2015, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] a proposed rule change to amend the Eighth Amended and Restated Operating Agreement of the Exchange to establish a Regulatory Oversight Committee as a Committee of the Board of Directors of the Exchange and make certain conforming amendments to Exchange Rules. The proposed rule change was published for comment in the **Federal Register** on June 30, 2015.[4] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [5] 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 Commission is extending this 45-day time period. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change.

Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates September 28, 2015, 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 Number SR–NYSE–2015–27).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Brent J. Fields,

Secretary.

[FR Doc. 2015–20154 Filed 8–14–15; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 75288 (June 24, 2015), 80 FR 37316.

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–101, OMB Control No. 3235–0082]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension: Form 11–K.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management Budget for extension and approval.

Form 11–K (17 CFR 249.311) is the annual report designed for use by employee stock purchase, savings and similar plans to comply with the reporting requirements under Section 15(d) of the Securities and Exchange Act of 1934 (the ''Exchange Act'') (15 U.S.C. 78o(d)). Section 15(d) establishes a periodic reporting obligation for every issuer of a class of securities registered under the Securities Act of 1933 (the ''Securities Act'') (15 U.S.C. 77a *et seq.*). Form 11–K provides employees of an issuer with financial information so that they can assess the performance of the investment vehicle or stock plan. Form 11–K takes approximately 30 burden hours per response and is filed by 1,761 respondents for total of 52,830 burden hours.

Written comments are invited on: (a) Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon,

100 F Street NE., Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

August 11, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–20159 Filed 8–14–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75661; File No. SR–NASDAQ–2015–094]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify NASDAQ Rule 7051 Fees Relating to Pricing for Direct Circuit Connections

August 11, 2015.

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 August 5, 2015, The NASDAQ Stock Market LLC (''NASDAQ'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II and III 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 the Substance of the Proposed Rule Change

NASDAQ is proposing to amend Rule 7051 to extend the waiver of installation fees assessed for Direct Circuit Connection to NASDAQ, and to waive ongoing monthly fees for direct connectivity to the Chicago, IL data center, for a limited time.

The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com,* at NASDAQ's principal office, 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, NASDAQ 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ is proposing to amend Rule 7051 entitled ''Direct Connectivity to Nasdaq'' to extend the waiver of installation fees for Direct Circuit Connection to Nasdaq (10Gb), Direct Circuit Connection to Nasdaq (supports up to 1Gb), and Direct Circuit Connection to Nasdaq (1Gb Ultra). The Exchange is also proposing to waive the related ongoing monthly fees assessed for these direct connectivity options to the Exchange's new Chicago, IL data center.[3] The Direct Circuit Connection options under Rule 7051 provide market participants with three optional means by which they may connect to NASDAQ.[4] The three Direct Circuit Connections are differentiated by the total capacity of the fiber connection (represented in Gigabytes or ''Gb'') and the type of switch used. A switch is a type of network hardware that acts as the ''gatekeeper'' for all clients' orders sent to the System[5] and orders them in sequence for entry into the System for execution. The 1Gb ''Ultra'' fiber connection offering uses lower latency[6] switches than the 1Gb fiber connection offering.[7]

The Exchange assesses separate installation and ongoing monthly fees for subscription to each option. For 1Gb connectivity, the Exchange assesses an installation fee of $1,500 and ongoing monthly fees of $2,500. For 10Gb connectivity, the Exchange charges an installation fee of $1,500 and ongoing monthly fees of $7,500. For 1Gb Ultra, the Exchange charges an installation fee of $1,500 and ongoing monthly fees of $2,500.

NASDAQ is relocating its Disaster Recovery (''DR'') location for the U.S. equities and options markets from Ashburn, VA to its new Chicago, IL data center beginning in August 2015 with completion of the move expected on November 9, 2015. NASDAQ has invested and installed new equipment in this data center for client connectivity and for the infrastructure of Exchange systems. NASDAQ has chosen Chicago as the location of its new DR data center as many other exchanges are using this same location for a DR or primary location and, as a result, many of our market participants have a presence or connection at this location, thus making it easier and less expensive for many market participants to connect to NASDAQ's DR location. In anticipation of the move and to facilitate transfer of connectivity from Ashburn, VA to Chicago, IL, the Exchange waived the installation fees for the months of April through July, 2015, for all three connectivity options so that both new subscriptions and customers transferring from one connectivity option to another during that time would not be assessed the installation fee.[8] The Exchange notes that the waiver allows members to move from one offering to another, or to move the location of their connectivity from one direct connectivity access point to another, with no penalty in the form of an installation fee. The Exchange is proposing to extend the waiver through November 9, 2015. To further facilitate use of the upgraded facility, the Exchange is also proposing to waive ongoing monthly fees for all three Direct Circuit Connectivity options for connectivity to the Chicago, IL data center. Waiver of the ongoing monthly fees will provide incentive to market participants to move their DR connectivity to Chicago, IL and test this connectivity prior to completion of the transfer of the DR functionality, and will also allow market participants that wish to connect to the Chicago, IL data center to do so smoothly with no penalty in the form of overlapping monthly direct connectivity fees.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[9] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[10] in particular, in that it provides for the equitable allocation

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Direct connectivity is offered through data centers in Carteret, NJ, Secaucus, NJ, Ashburn, VA, and Chicago, IL.

[4] The Exchange notes that there are several additional means by which market participants may connect to the Exchange, such as through the colocation facility or third parties.

[5] As defined in Rule 4701(a).

[6] The term ''latency'' for the purposes of this rule filing means a measure of the time it takes for an order to enter into a switch and then exit for entry into the System.

[7] Each of NASDAQ's connection offerings use different switches, but the switches are of uniform type within each offering (*i.e.,* all 1G connectivity options currently use the same switches). As a consequence, all client subscribers to a particular connectivity option receive the same latency in terms of the capabilities of their switches.

[8] *See* Securities Exchange Act Release No. 74680 (April 8, 2015), 80 FR 20035 (April 14, 2015) (SR–NASDAQ–2015–029).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4) and (5).

of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which NASDAQ operates or controls and 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 regulating, clearing, settling, processing information with respect to, and 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; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that extending the waiver of Direct Circuit Connectivity installation fees is reasonable because it will continue to enable market participants to move from one direct connectivity offering to another, or to move the location of their connectivity from one direct connectivity access point to another, with no penalty in the form of an installation fee. Similarly, the Exchange believes that the time-limited waiver of ongoing monthly fees for connectivity to the Chicago, IL data center is reasonable because the Exchange is moving its DR location from Ashburn, VA to Chicago, IL, which is expected to be completed on November 9, 2015. As such, to continue DR connectivity, market participants must subscribe to new Direct Circuit Connectivity to the Chicago, IL data center and test such connectivity prior to cancellation of their existing Ashburn, VA direct connectivity subscription. The Exchange believes that the proposed fee waivers are equitable and do not unfairly discriminate because they are of limited duration and designed to apply to market participants that wish to utilize the new direct connectivity location and/or are affected by the Exchange's determination to move trading and DR functionality from the Ashburn, VA data center. Moreover, the Exchange notes that the installation fee waiver applies to all three Direct Circuit Connectivity options, and therefore it believes that extension of the waiver is equitable and does not unfairly discriminate. Waiver of the installation fee will allow any market participant that wishes to move from their [sic] existing Direct Circuit Connectivity data center to the new Chicago, IL data center with no penalty. Waiver of the ongoing monthly fees for connectivity to Chicago, IL enables market participants to test the DR functionality in Chicago while still being connected to the Ashburn, VA location with no penalty in the form of overlapping monthly direct connectivity fees.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.[11] The Exchange believes that the proposed fee waivers are pro-competitive because they facilitate use of a new, upgraded data center, which will improve market resiliency and provide additional connectivity options to market participants. To the extent that the new data center makes NASDAQ more attractive to market participants over other exchanges and trading venues, it may provide incentive to such marketplaces to improve and add to their data centers, to the benefit of 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 change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and paragraph (f) of Rule 19b–4[13] 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.

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–2015–094 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–2015–094. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2015–094, and should be submitted on or before September 8, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Brent J. Fields,

Secretary.

[FR Doc. 2015–20155 Filed 8–14–15; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75664; File No. SR–BATS–2015–56]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing of a Proposal To List and Trade Shares of the ProShares Managed Futures Strategy ETF of the ProShares Trust Under BATS Rule 14.11 on BATS Exchange, Inc.

August 11, 2015.

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 July 30, 2015, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') 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 is proposing to list and trade shares of the ProShares Managed Futures Strategy ETF (the ''Fund'') of the ProShares Trust (the ''Trust'') under BATS 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 Web site at *www.batstrading.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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 list and trade the Shares under BATS Rule 14.11(i), which governs the listing and trading of Managed Fund Shares on the Exchange.[4] The Fund will be an actively managed fund that seeks to provide positive returns that are not directly correlated to broad equity or fixed income markets.

The Shares will be offered by the Trust, which was established as a Delaware statutory trust on May 29, 2002. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Fund on Form N–1A (''Registration Statement'') with the Commission.[5] The Commodity Futures Trading Commission (''CFTC'') has recently adopted substantial amendments to CFTC Rule 4.5 relating to the permissible exemptions and conditions for reliance on exemptions from registration as a commodity pool operator. As a result of the instruments that will be held by the Fund, the Adviser has registered as a Commodity Pool Operator (''CPO'') and is also a member of the National Futures Association (''NFA''). The Fund and ProShares Cayman Trust I, a wholly-owned subsidiary of the Fund organized under the laws of the Cayman Islands (the ''Subsidiary'' as further described herein) will be subject to regulation by the CFTC and NFA and additional disclosure, reporting and recordkeeping rules imposed upon commodity pools.

Description of the Shares and the Fund

ProShare Advisors LLC is the investment adviser (''PSA'' or ''Adviser'') to the Fund. JPMorgan Chase Bank, National Association is the administrator, custodian, fund account agent, index receipt agent and transfer agent for the Trust. SEI Investments Distribution Co. (''Distributor'') serves as the distributor for the Trust.

[4] The Commission approved BATS Rule 14.11(i) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[5] *See* Registration Statement on Form N–1A for the Trust, dated May 31, 2013 (File Nos. 333–89822 and 811–21114). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement. The Commission has issued an order granting certain exemptive relief to the Company under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act'') (the ''Exemptive Order''). *See* Investment Company Act Release No. 30562 (June 18, 2013) (File No. 812–14041).

BATS Rule 14.11(i)(7) provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[6] In addition, Rule 14.11(i)(7) further requires that personnel who make decisions on the investment company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable investment company portfolio. Rule 14.11(i)(7) is similar to BATS Rule 14.11(b)(5)(A)(i), however, Rule 14.11(i)(7) in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. The Adviser is not a registered broker-dealer, but is currently affiliated with a broker-dealer and, in the future may be affiliated with other broker dealers. The Adviser personnel who make decisions regarding the Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio. In the event that (a) the Adviser becomes a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant

[6] 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.

personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

ProShares Managed Futures Strategy ETF

According to the Registration Statement, the Fund seeks to achieve positive returns that are not directly correlated to broad equity or fixed income markets. The Fund uses the S&P® Strategic Futures Index as a performance benchmark (the ''Benchmark''). The Benchmark seeks to reflect trends (in either direction) in the commodity, foreign currency and fixed income markets by taking long or short positions in the related futures contracts. While the Fund generally will seek exposure to the commodity and financial markets included in the Benchmark, the Fund is not an index tracking ETF and will generally seek to enhance its performance by actively selecting investments for the Fund with varying maturities from the underlying components of the Benchmark.

There can be no assurance that the Fund's performance will exceed the performance of the Benchmark at any time. The Fund is not sponsored, endorsed, sold or promoted by S&P®. S&P's® only relationship to the Fund is the licensing of certain service marks and service names of S&P® and of the Benchmark, which is determined, composed and calculated by S&P® without regard to the Fund's investment advisor or the Fund. S&P® has no obligation to take the needs of the Fund's investment advisor or the Fund into consideration in determining, composing or calculating the Benchmark.

Under normal market conditions,[7] the Fund invests in a portfolio of exchange-traded commodity futures contracts (''Commodity Futures Contracts'') and exchange-traded currency and U.S. Treasury futures contracts (''Financial Futures Contracts'') (collectively, ''Futures Contracts'').

The Fund, in part through the Subsidiary, attempts to capture the economic benefit derived from rising and declining trends based on the price changes of these Futures Contracts. Each month, the Fund's investments will generally be positioned long or short based on a comparison of the recent returns of each Futures Contract with its own seven-month weighted moving average return. To be ''long'' means to hold or have long exposure to an asset with the expectation that its value will increase over time. To be ''short'' means to sell or have short exposure to an asset with the expectation that it will fall in value. The Fund will benefit if it is long an asset that increases in value or is short an asset that decreases in value. Conversely, the Fund will be adversely impacted if it is long an asset that decreases in value or short an asset that increases in value.

The following table describes each of the commodities, currencies and U.S. Treasuries underlying the futures contracts included in the Benchmark as of June 30, 2015. The table also provides each instrument's trading hours, exchange and ticker symbol. This table is subject to change:

Sector	Weight (%)	Component	Weight (%)	Exchange	Trading hours[8]
Energy	6.99	Light Crude	1.31	NYMEX (CME)	6:00 p.m.–5: 15 p.m. next day.
		Heating Oil	1.78	NYMEX (CME)	6:00 p.m.–5: 15 p.m. next day.
		RBOB Gasoline	1.64%	NYMEX (CME)	6:00 p.m.–5: 15 p.m. next day.
		Natural Gas	2.26%	NYMEX (CME)	6:00 p.m.–5: 15 p.m. next day.
Industrial Metals	3.64%	Copper	3.64%	COMEX (CME)	6:00 p.m.–5: 15 p.m. next day.
Precious Metals	3.87%	Gold	3.37%	COMEX (CME)	6:00 p.m.–5: 15 p.m. next day.
		Silver	1.76%	COMEX (CME)	6:00 p.m.–5: 15 p.m. next day.
Livestock	8.72%	Lean Hogs	3.95%	CME	10:05 a.m.–2:55 p.m.; Daily trading halts: 5:00 p.m.–6:00p.m.
		Live Cattle	4.77%	CME	10:05 a.m.–2:55 p.m. Daily trading halts 5:00 p.m.–6:00 p.m.

INDEX WEIGHTS

Sector	Weight (%)	Component	Weight (%)	Exchange	Trading hours
Grains	8.60	Corn	2.73	CBOT (CME)	8:00 p.m.–2:20 p.m. next day. Daily trading halt from 8:45 am to 9:30 a.m.
		Soybeans	3.10	CBOT (CME)	8:00 p.m.–2:20 p.m. next day. Daily trading halt from 8:45 a.m. to 9:30 a.m.
		Wheat	2.77	CBOT (CME)	8:00 p.m.–2:20 p.m. next day. Daily trading halt from 8:45 a.m. to 9:30 a.m.
Softs	13.01	Coffee	2.11	ICE	4:15 a.m.–1:30 p.m.
		Cocoa	4.76	ICE	4:45 a.m.–1:30 p.m.
		Sugar	2.72	ICE	3:30 a.m.–1:00 p.m.
		Cotton	3.42	ICE	9:00 p.m.–2:20 p.m. next day.
Australian Dollar	4.37	Australian Dollar.		CME	6:00 p.m.–5:15 p.m. next day.
British Pound	6.28	British Pound		CME	6:00 p.m.–5:15 p.m. next day.
Canadian Dollar	4.73	Canadian Dollar		CME	6:00 p.m.–5:15 p.m. next day.
Euro	4.56	Euro		CME	6:00 p.m.–5:15 p.m. Next day.

[7] The term ''under normal market conditions'' includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income markets, futures markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or manmade disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

[8] All times are E.T., inclusive of electronic and open outcry trading sessions, as applicable.

INDEX WEIGHTS—Continued

Sector	Weight (%)	Component	Weight (%)	Exchange	Trading hours
Japanese Yen ..	5.95	Japanese Yen		CME	6:00 p.m.–5:15 p.m. Next day.
Swiss Franc	3.39	Swiss Franc		CME	6:00 p.m.–5:15 p.m. Next day.
U.S. Treasury Notes [9].	14.58	U.S. Treasury Notes.		CBOT (CME) ...	6:00 p.m.–5:00 p.m. Next day.
U.S. Treasury Bonds [10].	10.04	U.S. Treasury Bonds.		CBOT (CME) ...	6:00 p.m.–5:00 p.m. Next day.
	100	.....	100		

In order to achieve its investment objective, the Fund will invest in: (i) Futures Contracts; [11] and/or (ii) under limited circumstances (as further described herein), swap agreements whose value is derived from the level of the Benchmark, other indexes, one or more futures contracts or their underlying reference assets. The Fund may also invest up to 100% of its assets in cash or cash equivalents such as U.S. Treasury securities or other high credit quality short-term fixed-income or similar securities (including shares of money market funds, bank deposits, bank money market accounts, certain variable rate-demand notes, and repurchase agreements collateralized by government securities) for direct investment or as collateral for the Futures Contracts or swap agreements.

The Adviser does not expect that the Fund will invest directly in any commodity or currency. In the event position accountability rules or position limits with respect to a Futures Contract are reached with respect to a Fund, the Adviser may, in its commercially reasonable judgment, obtain exposure through swaps whose value is derived from the level of the Benchmark, other Indexes, one or more Futures Contracts or their underlying reference assets, or invest in other futures contracts or swaps if such instruments tend to exhibit trading prices or returns that will further the investment objective of the Fund.[12] The Fund may also invest in swaps if the market for a specific Futures Contract experiences emergencies (*e.g.,* natural disaster, terrorist attack, or an act of God) or disruptions (*e.g.,* a trading halt or a flash crash) that would prevent the Fund from obtaining the appropriate amount of investment exposure to the affected Futures Contracts or other futures contracts directly.[13]

According to the Registration Statement, the Fund will invest a substantial portion of its assets in fixed income securities that include U.S. government and agency securities, money market instruments,[14] overnight and fixed-term repurchase agreements, cash and other cash equivalents. The Fund will use the fixed-income securities as investments and to meet asset coverage tests resulting from the Subsidiary's derivative exposure on a day-to-day basis. As a whole, the Fund's investments are meant to achieve its investment objective within the limitations of the federal tax requirements applicable to regulated investment companies.

The Fund expects to gain exposure to certain of these investments by investing a portion of its assets in the Subsidiary. The Subsidiary will be advised by the Adviser.[15] The Fund's investment in the Subsidiary is intended to provide the Fund with exposure to markets (in general, the commodity markets) within the limits of current federal income tax laws applicable to investment companies such as the Fund, which limit the ability of investment companies to invest directly in certain Futures Contracts. The Subsidiary will have the same investment objective as the Fund. Except as otherwise noted, references to the Fund's investments may also be deemed to include the Fund's indirect investments through the Subsidiary. The Fund will invest up to 25% of its total assets in the Subsidiary.

The Fund intends to qualify each year as a regulated investment company (a ''RIC'') under Subchapter M of the Internal Revenue Code of 1986, as amended.[16] The Fund will invest its assets (including via the Subsidiary), and otherwise conduct its operations, in a manner that is intended to satisfy the qualifying income, diversification and distribution requirements necessary to establish and maintain RIC qualification under Subchapter M. Aside from its investments in the Subsidiary, The Fund will not invest in options or non-U.S. equity securities.

Additional Information Regarding the Benchmark

Developed by S&P® and launched on August 14, 2014, the Benchmark is a long/short rules-based investable index that seeks to capture the economic benefit derived from both rising and declining trends in futures prices. The Benchmark is typically composed of futures contracts representing unleveraged long or short positions in the commodity and financial markets.

The weight assigned to each futures contract in the Benchmark is determined on a monthly basis, and implemented each month in an index rebalancing. Weights are determined using a proprietary risk-weighting methodology that measures the risk exposure of the futures contracts included in the Benchmark and then weights each futures contract so that it

[9] ''U.S. Treasury Notes'' refers to 10 year U.S. Treasury Note futures.

[10] ''U.S. Treasury Bonds'' refers to those futures with underlying bonds of a remaining term to call or maturity of 15–25 years.

[11] Futures Contracts will be the same type of contracts as the Index Components, but the expiration dates of such Futures Contracts may differ from the expiration dates of the Index Components at any given point in time.

[12] To the extent practicable, the Fund will invest in swaps cleared through the facilities of a centralized clearing house.

[13] The Adviser will also attempt to mitigate the Fund's credit risk by transacting only with large, well-capitalized institutions using measures designed to determine the creditworthiness of a counterparty. The Adviser will take various steps to limit counterparty credit risk, as described in the Registration Statement.

[14] The Fund may invest in shares of money market funds to the extent permitted by the 1940 Act.

[15] The Subsidiary is not registered under the 1940 Act and is not directly subject to its investor protections, except as noted in the Registration Statement. However, the Subsidiary is wholly-owned and controlled by the Fund and is advised by the Adviser. Therefore, because of the Fund's ownership and control of the Subsidiary, the Subsidiary would not take action contrary to the interests of the Fund or its shareholders. The Fund's Board of Trustees (''Board'') has oversight responsibility for the investment activities of the Fund, including its expected investment in the Subsidiary, and the Fund's role as the sole shareholder of the Subsidiary. The Adviser receives no additional compensation for managing the assets of the Subsidiary. The Subsidiary will also enter into separate contracts for the provision of custody, transfer agency, and accounting agent services with the same or with affiliates of the same service providers that provide those services to the Fund.

[16] 26 U.S.C. 851.

contributes the same level of risk to the Benchmark.

The Benchmark's exposure to futures contracts are not long-only, but are either short or long based on a comparison of the price change in the contract during the most recent month to a seven-month exponential weighted moving average price change of that contact. During the monthly rebalancing, the Benchmark also ''rolls'' certain of its positions in futures contracts from the current contract to a contract further from settlement.

Each month, S&P® will determine whether a futures contract that is a part of the Benchmark should be either a long or short position by comparing the price change of the most recent month (the ''First Month Price Change'') of the futures contract to the seven-month exponential weighted moving average price change (the ''Seven Month Price Change''). Long positions are tracked when a futures contract's First Month Price Change is greater than or equal to the Seven Month Price Change. Short positions are tracked when a futures contract's First Month Price Change is less than the Seven Month Price Change. The First Month Price Change of each futures contract is calculated by calculating the percentage difference of each futures contract's price on the last PDD (as defined below) relative to the current PDD.

When calculating the Seven Month Price Change, each month's price input is represented as the monthly percentage change of a futures contract price which is calculated in the same manner as the First Month Price Change. Monthly positions are determined on the second to last Benchmark business day of the month (defined as the position determination date, or ''PDD'') when the monthly percentage change of a futures contract's price is compared to past monthly price changes, exponentially weighted to give greatest weight to the most recent return and least weight to the return seven months prior. The weighted sum of the percentage changes of all futures contract prices in the Benchmark equals the daily movement of the Benchmark. To create an exponential average for comparison, price inputs (percentage change from current and previous PDDs) are weighted per the schedule below. Due to this weighting methodology, current price movements are more important than those of the more distant past.

During this monthly rebalancing, the Benchmark will also ''roll'' certain of its positions from the current contract to a contract further from settlement. In order to maintain consistent exposure to the futures contracts that compose the Benchmark, each futures contract must be sold prior to its expiration date and replaced by a contract maturing at a specified date in the future. This process is known as ''rolling.'' The futures contracts that are a part of the Benchmark are rolled periodically. The rolls are implemented pursuant to a roll schedule over a five-day period from the first (1st) through the fifth (5th) index business days of the month. An index business day is any day on which the majority of the futures contracts included in the Benchmark are open for official trading and official settlement prices are provided, excluding holidays and weekends.

In order to mitigate the potential negative impact of contango on long commodity positions, certain futures contracts in commodities will be rolled according to an ''enhanced'' rolling methodology. This methodology seeks to modify the normal roll methodology for futures contracts in the energy sector when such long position would be materially and negatively impacted by contango. In addition, the methodology identifies seasonal factors applicable to both the energy and agricultural futures markets and implements a modified roll to mitigate potential costs of such seasonal impacts.

Other Portfolio Holdings

In addition to the instruments described above, the Fund will invest in money market instruments [17] in a manner consistent with its investment objective in order to generate additional returns, to help manage cash flows in and out of the Fund, such as in connection with payment of dividends or expenses, to satisfy margin requirements, and to provide collateral or to otherwise back investments Futures Contracts.

Investment Restrictions

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment) deemed illiquid by the Adviser [18] under the 1940 Act.[19] The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets include assets subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.

The Fund's investments will be consistent with the Fund's investment objective and will not be used to achieve leveraged or inverse leveraged returns (*i.e.* two times or three times the Fund's benchmark).

Net Asset Value

According to the Registration Statement, the net asset value (''NAV'') of the Shares of the Fund will be calculated by dividing the value of the net assets of the Fund (*i.e.,* the value of its total assets less total liabilities) by the total number of Shares outstanding. Expenses and fees, including the management and administration fees, are accrued daily and taken into account for purposes of determining NAV. The NAV of the Fund is generally determined at 3:00 p.m. Eastern Time each business day when the Exchange is open for trading. If the Exchange or market on which the Fund's investments are primarily traded closes early, the NAV may be calculated prior to its normal calculation time. Creation/redemption transaction order time cutoffs (as further described below) would also be accelerated.

Securities and other assets are generally valued at their market price using information provided by a pricing service or market quotations. Certain short-term securities are valued on the basis of amortized cost. Futures

[17] The specific money market instruments are Treasury securities and repurchase agreements and, in the future, may include money market fund shares.

[18] In reaching liquidity decisions, the Adviser may consider the following factors: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace trades (*e.g.,* the time needed to dispose of the security, the method of soliciting offers, and the mechanics of transfer).

[19] The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. *See also,* Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding ''Restricted Securities''); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

Contracts are generally valued at their settlement price as determined by the relevant exchange. The settlement value of the Fund's swap agreements will be determined by applying the then-current disseminated value for the Index Components to the terms of the Fund's swap agreements. Repurchase agreements are generally valued at cost. U.S government securities are generally priced at a quoted market price from an active market, generally the midpoint between the bid/ask quotes. For U.S. government securities that mature within sixty days, amortized cost may be used to approximate fair value. Money market funds would generally be valued at their current Net Asset Value per share, typically $1.00 per share. Certain short-term debt securities will be valued on the basis of amortized cost.

When the Adviser determines that the price of a security or derivative is not readily available or deems the price unreliable, it may, in good faith, establish a fair value for that security or derivative in accordance with procedures established by and under the general supervision and responsibility of the Board. The use of a fair valuation method may be appropriate if, for example, market quotations do not accurately reflect fair value for an investment, a trading halt closes an exchange or market early, or other events result in an exchange or market delaying its normal close. The Adviser may consider applying appropriate valuation methodologies, which may include discounts of market value of similar freely traded securities, yields to maturity, or any other appropriate method. In determining the appropriate methodology, the Adviser may consider all relevant factors, including, among other things: Fundamental analytical data; the types of securities affected; pricing history of the security; whether dealer quotations are available; liquidity of the market; news or other events; and other factors the Adviser deems relevant.

For more information regarding the valuation of Fund investments in calculating the Fund's NAV, see the Registration Statement.

The Shares

The Fund will issue and redeem Shares on a continuous basis at the NAV per Share only in large blocks of a specified number of Shares or multiples thereof (''Creation Units'') in transactions with authorized participants who have entered into agreements with the Distributor. The Adviser currently anticipates that a Creation Unit will consist of 25,000 Shares, though this number may change from time to time, including prior to listing of the Shares. The exact number of Shares that will constitute a Creation Unit will be disclosed in the Registration Statement. Once created, Shares of the Fund trade on the secondary market in amounts less than a Creation Unit.

Although the Adviser anticipates that purchases and redemptions for Creation Units will generally be executed on an all-cash basis, the consideration for purchase of Creation Units of the Fund may consist of an in-kind deposit of a designated portfolio of securities (including any portion of such assets for which cash may be substituted) (*i.e.,* the ''Deposit Assets''), and the ''Cash Component'' computed as described below. Together, the Deposit Assets and the Cash Component constitute the ''Fund Deposit,'' which represents the minimum initial and subsequent investment amount for a Creation Unit of the Fund. The specific terms surrounding the creation and redemption of shares are at the discretion of the Adviser.

The Deposit Assets and Fund Securities (as defined below), as the case may be, in connection with a purchase or redemption of a Creation Unit, generally will correspond pro rata, to the extent practicable, to the assets held by the Fund.

The Cash Component will be an amount equal to the difference between the NAV of the Shares (per Creation Unit) and the ''Deposit Amount,'' which will be an amount equal to the market value of the Deposit Assets, and serve to compensate for any differences between the NAV per Creation Unit and the Deposit Amount. The Fund generally offers Creation Units partially or entirely for cash. PSA will make available through the National Securities Clearing Corporation (''NSCC'') on each business day, prior to the opening of business on the Exchange, the list of names and the required number or par value of each Deposit Security and the amount of the Cash Component to be included in the current Fund Deposit (based on information as of the end of the previous business day) for the Fund.

The identity and number or par value of the Deposit Assets may change pursuant to changes in the composition of the Fund's portfolio as rebalancing adjustments and corporate action events occur from time to time. The composition of the Deposit Assets may also change in response to adjustments to the weighting or composition of the holdings of the Fund.

The Fund reserves the right to permit or require the substitution of a ''cash in lieu'' amount to be added to the Cash Component to replace any Deposit Security that may not be available in sufficient quantity for delivery or that may not be eligible for transfer through the Depository Trust Company (''DTC'') or the clearing process through the NSCC.

Except as noted below, all creation orders must be placed for one or more Creation Units and must be received by the Distributor at a time specified by the Adviser. Currently, such orders must be received in proper form no later than 2:30 p.m. Eastern Time on the date such order is placed in order for creation of Creation Units to be effected based on the NAV of Shares of the Fund as next determined on such date after receipt of the order in proper form. The ''Settlement Date'' is generally the third business day after the transmittal date. On days when the Exchange or the bond markets close earlier than normal, the Fund may require orders to create or to redeem Creation Units to be placed earlier in the day.

Fund Deposits must be delivered through either the Continuous Net Settlement facility of the NSCC, the Federal Reserve System (for cash and government securities), through DTC (for corporate and municipal securities), or through a central depository account, such as with Euroclear or DTC, maintained by State Street or a sub-custodian (a ''Central Depository Account''), in any case at the discretion of the Adviser, by an authorized participant. Any portion of a Fund Deposit that may not be delivered through the NSCC, Federal Reserve System or DTC must be delivered through a Central Depository Account.

A standard creation transaction fee may be imposed to offset the transfer and other transaction costs associated with the issuance of Creation Units.

Shares of the Fund may be redeemed only in Creation Units at their NAV next determined after receipt of a redemption request in proper form by the Distributor and only on a business day. PSA will make available through the NSCC, prior to the opening of business on the Exchange on each business day, the designated portfolio of securities (including any portion of such securities for which cash may be substituted) that will be applicable (subject to possible amendment or correction) to redemption requests received in proper form on that day (''Fund Securities''). The redemption proceeds for a Creation Unit generally will consist of a specified amount of cash less a redemption transaction fee. The Fund generally will redeem Creation Units entirely for cash.

A standard redemption transaction fee may be imposed to offset transfer and other transaction costs that may be incurred by the Fund.

Redemption requests for Creation Units of the Fund must be submitted to the Distributor by or through an authorized participant by a time specified by the Adviser. Currently, such requests must be received no later than 10:45 a.m. Eastern Time on any business day, in order to receive that day's NAV. The authorized participant must transmit the request for redemption in the form required by the Fund to the Distributor in accordance with procedures set forth in the authorized participant agreement.

Additional information regarding the Shares and the Fund, including investment strategies, risks, creation and redemption procedures, fees and expenses, portfolio holdings disclosure policies, distributions, taxes and reports to be distributed to beneficial owners of the Shares can be found in the Registration Statement or on the Web site for the Fund (*www.ProShares.com*), as applicable.

Availability of Information

The Fund's Web site, which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Web sites will include additional quantitative information updated on a daily basis, including, for the Fund: (1) The prior business day's reported NAV, the closing market price or the midpoint of the bid/ask spread at the time of calculation of such NAV (the ''Bid/Ask price''),[20] daily trading volume, and a calculation of the premium and discount of the closing market price or Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily closing price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. Daily trading volume information will be available in the financial section of newspapers, through subscription services such as Bloomberg, Thomson Reuters, and International Data Corporation, which can be accessed by authorized participants and other investors, as well as through other electronic services, including major public Web sites. On each business day, before commencement of trading in Shares during Regular Trading Hours [21] on the Exchange, the Fund will disclose on its Web site the identities and quantities of the portfolio Futures Contracts and other assets (the ''Disclosed Portfolio'') held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the business day.[22] The Disclosed Portfolio will include, as applicable, the names, quantity, exposure value (notional value + gains/losses), and market value of the Futures Contracts and other assets held by the Fund and the characteristics of such assets. The Web site and information will be publicly available at no charge.

In addition, for the Fund, an estimated value, defined in BATS Rule 14.11(i)(3)(C) as the ''Intraday Indicative Value,'' that reflects an estimated intraday value of the Fund's portfolio, will be disseminated. Moreover, the Intraday Indicative Value will be based upon the current value for the components of the Disclosed Portfolio and will be updated and widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Regular Trading Hours.[23] In addition, the quotations of certain of the Fund's holdings may not be updated during U.S. trading hours if such holdings do not trade in the United States or if updated prices cannot be ascertained.

The dissemination of the Intraday Indicative Value, together with the Disclosed Portfolio, will allow investors to determine the value of the underlying portfolio of the Fund on a daily basis and provide an estimate of that value throughout the trading day.

Intraday price quotations on repurchase agreements and U.S. Government securities of the type held by the Fund are available from major broker-dealer firms and from third-parties, which may provide prices free with a time delay, or ''live'' with a paid fee. For Futures Contracts, such intraday information is available directly from the applicable listing exchange. Intraday price information is also available through subscription services, such as Bloomberg and Thomson Reuters, which can be accessed by authorized participants and other investors. Money market fund shares are not generally priced or quoted on an intraday basis.

Information regarding market price and volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The previous day's closing price and trading volume information for the Shares will be generally available daily in the print and online financial press. Quotation and last sale information for the Shares will be available on the facilities of the CTA.

Initial and Continued Listing

The Shares will be subject to BATS Rule 14.11(i), which sets forth the initial and continued listing criteria applicable to Managed Fund Shares. The Exchange represents that, for initial and/or continued listing, the Fund must be in compliance with Rule 10A–3 under the Act.[24] A minimum of 100,000 Shares 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 will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares the Fund. The Exchange will halt trading in the Shares under the conditions specified in BATS Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the Futures Contracts and other assets composing the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which Shares of the Fund may be halted.

Trading Rules

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

[20] The Bid/Ask Price of the Fund will be determined using the midpoint of the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund and its service providers.

[21] Regular Trading Hours are 9:30 a.m. to 4:00 p.m. Eastern Time.

[22] Under accounting procedures to be followed by the Fund, trades made on the prior business day (''T'') will be booked and reflected in NAV on the current business day (''T+1''). Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

[23] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available Intraday Indicative Values published via the Consolidated Tape Association (''CTA'') or other data feeds.

[24] *See* 17 CFR 240.10A–3.

equity securities. BATS will allow trading in the Shares from 8:00 a.m. until 5:00 p.m. Eastern Time. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in BATS Rule 11.11(a), the minimum price variation for quoting and entry of orders in Managed Fund Shares traded on the Exchange is $0.01, with the exception of securities that are priced less than $1.00, for which the minimum price variation for order entry is $0.0001.

Surveillance

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. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Managed Fund Shares. The Exchange may obtain information regarding trading in the Shares and the underlying futures via the Intermarket Surveillance Group (''ISG'') from other exchanges who are members or affiliates of the ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[25] In addition, the Exchange is able to access, as needed, trade information for certain fixed income instruments reported to FINRA's Trade Reporting and Compliance Engine (''TRACE''). The Exchange prohibits the distribution of material non-public information by its employees.

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) BATS Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (3) how information regarding the Intraday Indicative Value is disseminated; (4) the risks involved in trading the Shares during the Pre-Opening[26] and After Hours Trading Sessions[27] when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (5) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Fund. Members purchasing Shares from the Fund for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act.

In addition, the Information Circular will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Information Circular will also disclose the trading hours of the Shares of the Fund and the applicable NAV calculation time for the Shares. The Information Circular will disclose that information about the Shares of the Fund will be publicly available on the Fund's Web site. In addition, the Information Circular will reference that the Trust is subject to various fees and expenses described in the Registration Statement.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[28] in general and Section 6(b)(5) of the Act[29] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in BATS Rule 14.11(i). 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. If the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser to the investment company shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio. The Adviser is not a registered broker-dealer, but is affiliated with a broker-dealer and has implemented a ''fire wall'' with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the Fund's portfolio. The Exchange may obtain information regarding trading in the Shares and the underlying futures via the ISG from other exchanges who are members or affiliates of the ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[30] In addition, the Exchange is able to access, as needed, trade information for certain fixed income instruments reported to FINRA's TRACE.

According to the Registration Statement, the Fund expects that, under normal circumstances, it will have at least 80% of its assets invested, either directly or indirectly via the Subsidiary, in Futures Contracts. The Fund also may invest its net assets in money market instruments as collateral for the Futures Contracts and in order to help manage cash flows in and out of the Fund.

Additionally, the Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment). The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets include assets subject to contractual or other

[25] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.* The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange also notes that all of the futures contracts in the Disclosed Portfolio for the Fund will trade on markets that are a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[26] The Pre-Opening Session is from 8:00 a.m. to 9:30 a.m. Eastern Time.

[27] The After Hours Trading Session is from 4:00 p.m. to 5:00 p.m. Eastern Time.

[28] 15 U.S.C. 78f.

[29] 15 U.S.C. 78f(b)(5).

[30] *See* note 24, *supra.*

restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. Moreover, the Intraday Indicative Value will be disseminated by one or more major market data vendors at least every 15 seconds during Regular Trading Hours. On each business day, before commencement of trading in Shares during Regular Trading Hours, the Fund will disclose on its Web site the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day. Pricing information will be available on the Fund's Web site including: (1) The prior business day's reported NAV, the Bid/Ask Price of the Fund, and a calculation of the premium and discount of the Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. Additionally, information regarding market price and trading of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last sale information for the Shares will be available on the facilities of the CTA. The Web site for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Trading in Shares of the Fund will be halted under the conditions specified in BATS Rule 11.18. Trading may also be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Finally, trading in the Shares will be subject to BATS Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which Shares of the Fund may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

Intraday price quotations on repurchase agreements and U.S. Government securities of the type held by the Fund are available from major broker-dealer firms and from third-parties, which may provide prices free with a time delay, or ''live'' with a paid fee. For Futures Contracts, such intraday information is available directly from the applicable listing exchange. Intraday price information is also available through subscription services, such as Bloomberg and Thomson Reuters, which can be accessed by authorized participants and other investors. Money market fund shares are not generally priced or quoted on an intraday basis.

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 additional types of actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and 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 as well as trade information for certain fixed income instruments as reported to FINRA's TRACE. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the 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 listing and trading of additional actively-managed exchange-traded products that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (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 Exchange 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–BATS–2015–56 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–BATS–2015–56. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2015–56 and should be submitted on or before September 8, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Brent J. Fields,

Secretary.

[FR Doc. 2015–20157 Filed 8–14–15; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Regulatory Fairness Hearing; Region IX—Springerville, Arizona

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open hearing of Region IX Small Business Owners and Business Leaders in Springerville, Arizona.

SUMMARY: The SBA, Office of the National Ombudsman is issuing this notice to announce the location, date and time of the Springerville, AZ Regulatory Fairness Hearing. This hearing is open to the public.

DATES: The hearing will be held on Wednesday, September 9, 2015, from 8:30 a.m. to 5:00 p.m. (MST).

ADDRESSES: The hearing will be at The American Legion, Post 30, 825 E. Main Street, Springerville, AZ 85938–5535.

SUPPLEMENTARY INFORMATION: Pursuant to the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121), Sec. 222, SBA announces the hearing for Small Business Owners, Business Leaders, Business Organizations, Trade Associations, Chambers of Commerce and related organizations serving small business concerns to report experiences regarding unfair or excessive Federal regulatory enforcement issues affecting their members.

FOR FURTHER INFORMATION CONTACT: The hearing is open to the public; however, advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation at the Springerville, AZ hearing must contact Doyel Shamley at *Doyel@vrcltd.us* or José Méndez by August 28, 2015 in writing, by fax, or email in order to be placed on the agenda. For further information, please contact José Méndez, Case Management Specialist, Office of the National Ombudsman, 409 3rd Street SW., Suite 7125, Washington, DC 20416, by fax (202) 481–5719, by email at *ombudsman-events@sba.gov,* by phone (202) 205–6178. Additionally, if you need accommodations because of a disability, translation services, or require additional information, please contact José Méndez as well at least 1 week in advance.

For more information on the Office of the National Ombudsman, see our Web site at *www.sba.gov/ombudsman.*

Dated: August 7, 2015.

Miguel J. L'Heureux,

SBA Committee Management Officer.

[FR Doc. 2015–20169 Filed 8–14–15; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 9224]

Culturally Significant Objects Imported for Exhibition Determinations: ''Painting the Modern Garden: Monet to Matisse'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E. O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Painting the Modern Garden: Monet to Matisse,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Cleveland Museum of Art, Cleveland, Ohio, from on or about October 6, 2015, until on or about January 5, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: August 6, 2015.

Evan Ryan,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–20259 Filed 8–14–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 9225]

Culturally Significant Objects Imported for Exhibition Determinations: ''Joaquín Torres-García: The Arcadian Modern'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E. O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Joaquín Torres-García: The Arcadian Modern,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Museum of Modern Art, New York, New York, from on or about October 25, 2015, until on or about February 15, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S.

[31] 17 CFR 200.30–3(a)(12).

Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: August 6, 2015.

Evan Ryan,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–20258 Filed 8–14–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 9223]

60-Day Notice of Proposed Information Collection: Request for Entry Into Children's Passport Issuance Alert Program

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATE(S): The Department will accept comments from the public up to *October 16, 2015.*

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

- *Web:* Persons with access to the Internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2015–0042'' in the search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: RiversDA@state.gov.*
- *Mail:* Send written comments to: U.S. Department of State, CA/OCS/PMO, SA–17, 10th Floor, Washington, DC 20036.
- *Fax:* 202–736–9111.
- *Hand Delivery or Courier:* U.S. Department of State, CA/OCS/PMO, 600 19th St. NW., 10th Floor, Washington, DC 20036.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Derek Rivers, Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS/PMO), U.S. Department of State, SA–17, 10th Floor, Washington, DC 20036 or at *RiversDA@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Request for Entry into Children's Passport Issuance Alert Program.
- *OMB Control Number:* 1405–0169.
- *Type of Request:* Extension.
- *Originating Office:* CA/OCS/PMO.
- *Form Number:* DS–3077.
- *Respondents:* Concerned parents or their agents, institutions, or courts.
- *Estimated Number of Respondents:* 6,000.
- *Estimated Number of Responses:* 6,000.
- *Average Hours per Response:* 30 minutes.
- *Total Estimated Burden:* 3,000 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the requests for information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection: The information requested will be used to support entry of the name of a minor (an unmarried person under 18) into the Children's Passport Issuance Alert Program (CPIAP). CPIAP provides a mechanism for parents or other persons with legal custody of a minor to obtain information regarding whether the Department has received a passport application for the minor. This program was developed as a means to prevent international abduction of a minor or to help prevent other travel of a minor without the consent of a parent or legal guardian. If a minor's name and other identifying information has been entered into the CPIAP, when the Department receives an application for a new, replacement, or renewed passport for the minor, the application will be placed on hold for up to 60 days and the Office of Children's Issues will attempt to notify the requestor of receipt of the application. Form DS–3077 will be primarily submitted by a parent or legal guardian of a minor. 22 C.F.R § 51.28 which is a regulation that implements the statutory two parent consent requirement and prescribes the bases for an exception is one of the main legal authorities that this form is based from.

Methodology: The completed form DS–3077 can be filled out online and printed or completed by hand. The form must be manually signed and submitted to the Office of Children's Issues by email, fax or mail.

Dated: July 29, 2015.

Michelle Bernier-Toth,

Managing Director, Bureau of Consular Affairs, Department of State.

[FR Doc. 2015–20241 Filed 8–14–15; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Government/Industry Aeronautical Charting Forum Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces the bi-annual meeting of the Federal Aviation Administration (FAA) Aeronautical Charting Forum (ACF) to discuss informational content and design of aeronautical charts and related products, as well as instrument flight procedures development policy and design criteria.

DATES: The ACF is separated into two distinct groups. The Instrument Procedures Group (IPG) will meet October 27, 2015 from 8:30 a.m. to 5:00 p.m. The Charting Group will meet October 28 and 29, 2015 from 8:30 a.m. to 5:00 p.m.

ADDRESSES: The meeting will be held at the United States Geological Survey (USGS) Headquarters at 12201 Sunrise Valley Drive, Reston, VA 20192.

FOR FURTHER INFORMATION CONTACT: For information relating to the Instrument Procedures Group, contact Thomas E. Schneider, FAA, Flight Procedures Standards Branch, AFS–420, 6500 South MacArthur Blvd., P.O. Box 25082, Oklahoma City, OK 73125; telephone: (405) 954–5852.

For information relating to the Charting Group, contact Valerie S.

Watson, FAA, Aeronautical Information Services, Governance & Standards, AJV–553, 1305 East-West Highway, SSMC4, Station 3409, Silver Spring, MD 20910; telephone: (301) 427–5155.

SUPPLEMENTARY INFORMATION: Pursuant to § 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II), notice is hereby given of a meeting of the FAA Aeronautical Charting Forum to be held from October 27 through October 29, 2015, from 8:30 a.m. to 5:00 p.m. at USGS Headquarters at 12201 Sunrise Valley Drive, Reston, VA 20192, in the Auditorium (Room 1C111).

The Instrument Procedures Group agenda will include briefings and discussions on recommendations regarding pilot procedures for instrument flight, as well as criteria, design, and developmental policy for instrument approach and departure procedures.

The Charting Group agenda will include briefings and discussions on recommendations regarding aeronautical charting specifications, flight information products, and new aeronautical charting and air traffic control initiatives. Attendance is open to the interested public, but will be limited to the space available.

Please note the following special security requirements for access to the USGS Headquarters. All visitors must enter at the Visitors Entrance and pass through security screening process. All packages, briefcases, handbags, etc. will be scanned. Visitors must sign in and present a picture I.D., such as a State's driver's license. The guard will then issue a visitor's badge which must be worn at all times.

All foreign national participants are required to have a passport. Additionally, not later than October 15, 2015, foreign national attendees must provide their name, country of citizenship, company/organization representing, passport number, passport expiration date, issuing country of passport, and country of the company/organization. Send the information to: Lance Christian via Email to: *lance.d.christian@nga.mil.* Foreign nationals who do not provide the required information will not be allowed entrance—NO EXCEPTIONS.

Attendees bringing laptop computers for use at during the conference are required to register their laptop when registering to enter the USGS facility. Attendees are to write the word ''laptop'' and the serial number on the sign-in beneath their printed name.

The public must make arrangements by October 8, 2015, to present oral statements at the meeting. The public may present written statements and/or new agenda items to the forum by providing a copy to the person listed in the **FOR FURTHER INFORMATION CONTACT** section not later than October 8, 2015. Public statements will only be considered if time permits.

Issued in Washington, DC, on August 6, 2015.

Valerie S. Watson,

Co-Chair, Aeronautical Charting Forum.

[FR Doc. 2015–20146 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

First Meeting: RTCA Special Committee 235 (SC 235)

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

ACTION: First Meeting Notice of RTCA Special Committee 235.

SUMMARY: The FAA is issuing this notice to advise the public of the first meeting of the RTCA Special Committee 235.

DATES: The meeting will be held October 21st–22nd from 9:00 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at RTCA Headquarters, 1150 18th Street NW., Suite 450, Washington, DC 20036, Tel: (202) 330–0680.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC, 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org* or Karan Hofmann, Program Director, RTCA, Inc., *khofmann@rtca.org,* (202) 330–0680.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the RTCA Special Committee 235. The agenda will include the following:

Wednesday, October 21, 2015

1. Welcome
2. Administrative Remarks
3. Introductions
4. Agenda Review
5. RTCA Overview Presentation
   a. Background on RTCA, MOPS, and Process
6. SC–235 Scope and Terms of Reference review
7. Overview of DO–227
8. SC–235 Structure and Organization of Work
9. Proposed Schedule
10. RTCA workspace presentation
11. Other Business
12. Date and Place of Next Meeting
13. Adjourn

Thursday, October 22, 2015

14. Continuation of Plenary or Working Group Session

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on August 13, 2015.

Latasha Robinson,

Management & Program Analyst, Next Generation, Enterprise Support Services Division, Federal Aviation Administration.

[FR Doc. 2015–20276 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Opportunity for Public Comment on Surplus Property Release at Madras Municipal Airport, Madras, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comments.

SUMMARY: Under the provisions of Title 49, U.S.C. Section 47153(c), notice is being given that the FAA is considering a request from the City of Madras, OR, to waive the surplus property requirements for approximately 1.07 acres of airport property located at Madras Municipal Airport, in Madras, OR.

The subject property is located away from the aeronautical area and currently vacant. The property will remain vacant of any structures, as it will be utilized for public road improvements and right of way purposes only. This release will allow the City to sell parcels of the airport property to businesses interested in the airport industrial park. There will be no actual proceeds generated from the proposed release of this property as it will be used for public road improvements and right-of-way purposes. It has been determined through study that the subject parcels will not be needed for aeronautical purposes.

DATES: Comments must be received on or before September 30, 2015.

ADDRESSES: Send comments on this document to Ms. Cayla Morgan at the Federal Aviation Administration, 1601 Lind Avenue SW., Renton, Washington, 98057–3356, Telephone 425–227–2653.

FOR FURTHER INFORMATION CONTACT: Documents are available for review by appointment by contacting Ms. Cayla Morgan, Telephone 425–227–2653, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, Washington.

Issued in Renton, Washington on August 11, 2015.

Joelle Briggs,

Assistant, Manager, Seattle Airports District Office.

[FR Doc. 2015–20289 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Buy America Waiver Notification

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for the use of non-domestic steel products contained in (1) Helical Bevel gearbox Rebuild kits for trail lock machinery, (2) Trail lock brake motors, (3) R1 and R2 Reducer Subcomponents, (4) Spherical Roller Bearings for bridge operating machinery, (5) Diesel Engine for Hydraulic Power Unit for emergency drive system, and (6) Hydraulic Vane Motor for emergency Hydraulic drive system in the State of New York.

DATES: The effective date of the waiver is August 18, 2015.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Gerald Yakowenko, FHWA Office of Program Administration, (202) 366–1562, or via email at *gerald.yakowenko@dot.gov.* For legal questions, please contact Mr. Jomar Maldonado, FHWA Office of the Chief Counsel, (202) 366–1373, or via email at *Jomar.Maldonado@dot.gov.* Office hours for the FHWA are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the Federal Register's home page at: *http://www.archives.gov* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara.*

Background

The FHWA's Buy America policy in 23 CFR 635.410 requires a domestic manufacturing process for any steel or iron products (including protective coatings) that are permanently incorporated in a Federal-aid construction project. The regulation also provides for a waiver of the Buy America requirements when the application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not sufficiently available. This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for use of non-domestic steel product contained in (1) Helical Bevel gearbox Rebuild kits for trail lock machinery, (2) Trail lock brake motors, (3) R1 and R2 Reducer Subcomponents, (4) Spherical Roller Bearings for bridge operating machinery, (5) Diesel Engine for Hydraulic Power Unit for emergency drive system, and (6) Hydraulic Vane Motor for emergency Hydraulic drive system in the State of New York.

In accordance with Division K, section 122 of the ''Consolidated and Further Continuing Appropriations Act, 2015'' (Pub. L. 113–235), FHWA published a notice of intent to issue a waiver on its Web site for non-domestic steel cable nets (*http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=109*) on June 18. The FHWA received no comments in response to the publication. During the 15-day comment period, FHWA conducted additional review to locate potential domestic manufacturers of (1) Helical Bevel gearbox Rebuild kits for trail lock machinery, (2) Trail lock brake motors, (3) R1 and R2 Reducer Subcomponents, (4) Spherical Roller Bearings for bridge operating machinery, (5) Diesel Engine for Hydraulic Power Unit for emergency drive system, and (6) Hydraulic Vane Motor for emergency Hydraulic drive system. Based on all the information available to the agency, FHWA concludes that there are no domestic manufacturers of (1) Helical Bevel gearbox Rebuild kits for trail lock machinery, (2) Trail lock brake motors, (3) R1 and R2 Reducer Subcomponents, (4) Spherical Roller Bearings for bridge operating machinery, (5) Diesel Engine for Hydraulic Power Unit for emergency drive system, and (6) Hydraulic Vane Motor for emergency Hydraulic drive system.

In accordance with the provisions of section 117 of the SAFETEA–LU Technical Corrections Act of 2008 (Pub. L. 110–244, 122 Stat. 1572), FHWA is providing this notice as its finding that a waiver of Buy America requirements is appropriate. The FHWA invites public comment on this finding for an additional 15 days following the effective date of the finding. Comments may be submitted to FHWA's Web site via the link provided to the New York waiver page noted above.

(Authority: 23 U.S.C. 313; Pub. L. 110–161, 23 CFR 635.410)

Issued on: August 10, 2015.

Gregory G. Nadeau,

Acting Administrator, Federal Highway Administration.

[FR Doc. 2015–20183 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2015–0060]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA confirms its decision to exempt 49 individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions were effective on July 7, 2015. The exemptions expire on July 7, 2017.

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Room W64–224, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue

SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Background

On June 4, 2015, FMCSA published a notice of receipt of Federal diabetes exemption applications from 49 individuals and requested comments from the public (80 FR 31949). The public comment period closed on July 6, 2015, and no comments were received.

FMCSA has evaluated the eligibility of the 49 applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

Diabetes Mellitus and Driving Experience of the Applicants

The Agency established the current requirement for diabetes in 1970 because several risk studies indicated that drivers with diabetes had a higher rate of crash involvement than the general population. The diabetes rule provides that ''A person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control'' (49 CFR 391.41(b)(3)).

FMCSA established its diabetes exemption program, based on the Agency's July 2000 study entitled ''A Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin-Treated Diabetes Mellitus to Operate in Interstate Commerce as Directed by the Transportation Act for the 21st Century.'' The report concluded that a safe and practicable protocol to allow some drivers with ITDM to operate CMVs is feasible. The September 3, 2003 (68 FR 52441), **Federal Register** notice in conjunction with the November 8, 2005 (70 FR 67777), **Federal Register** notice provides the current protocol for allowing such drivers to operate CMVs in interstate commerce.

These 49 applicants have had ITDM over a range of one to 43 years. These applicants report no severe hypoglycemic reactions resulting in loss of consciousness or seizure, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning symptoms, in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the past 5 years. In each case, an endocrinologist verified that the driver has demonstrated a willingness to properly monitor and manage his/her diabetes mellitus, received education related to diabetes management, and is on a stable insulin regimen. These drivers report no other disqualifying conditions, including diabetes-related complications. Each meets the vision requirement at 49 CFR 391.41(b)(10).

The qualifications and medical condition of each applicant were stated and discussed in detail in the June 4, 2015, **Federal Register** notice and they will not be repeated in this notice.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the diabetes requirement in 49 CFR 391.41(b)(3) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered medical reports about the applicants' ITDM and vision, and reviewed the treating endocrinologists' medical opinion related to the ability of the driver to safely operate a CMV while using insulin.

Consequently, FMCSA finds that in each case exempting these applicants from the diabetes requirement in 49 CFR 391.41(b)(3) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and they include the following: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Conclusion

Based upon its evaluation of the 49 exemption applications, FMCSA exempts the following drivers from the diabetes requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above 949 CFR 391.64(b)):

Craig S. Barton (UT)
Kevin H. Bennerson (NY)
Eugene Butler (AR)
Dominick M. Ciuffreda (MA)
Allen D. Clise (MD)
John W. Dillard (TX)
Derek P. Elkins (AZ)
Joshua J. Ellett (IN)
Raymond C. Erschen (PA)
Dominic C. Frisina (PA)
David D. Gambill (NC)
Dennis T. Gannon (NJ)
Arnold W. Geske (MN)
Alan G. Gladhill (MD)
Richard A. Hall (IL)
Dwight L. Hawkins (NC)
Craig L. Jackson (WY)
Wayne A. Jadezuk (NY)
Lee L. Kropp (WI)
Douglas B. Lampela (MI)
David E. Lawton (MA)
Babe A. Lisai (NY)
Adrian Martinez-Alba (TX)
Robert S. Medberry (OH)
Daniel Mendolia (NY)
Gary L. Mjoness (ND)
Marty G. Niles (MT)
Timothy W. Olden (NJ)
John Palermo (NJ)
Dennis P. Pantone (NY)
John N. Peterson (WI)
Robert L. Potter, Jr. (NH)
Todd M. Raether (NE)
Michael A. Ramsey (CT)
Gene P. Rhodes Sr. (PA)
Peter B. Rzadkowski, Jr. (IL)
Jeffrey J. Salvador (MI)
Michael A. Scavotto (MA)
Michael Schmidt (PA)
Steven J. Schmitt (MN)
Carl J. Schneider (PA)
John R. Sherbondy (PA)
Douglas J. Smith (NY)

Johnathan C. Steffes (CA)
Carmen M. Stellitano (PA)
Andy L. Strommenger (CO)
Jared Villa (ND)
Robert T. Warriner (NJ)
Ellis E. Wilkins (MA)

In accordance with 49 U.S.C. 31136(e) and 31315 each exemption is valid for two years unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315. If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: August 7, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–20188 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2014–0373]

Qualification of Drivers; Exemption Applications; Narcolepsy

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denial of exemption applications.

SUMMARY: FMCSA announces its decision to deny applications from three individuals seeking exemptions from the prohibitions against operating a commercial motor vehicle (CMV) in interstate commerce by persons with: (1) Either a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to operate a CMV safely, or (2) a mental, nervous, organic, or functional disease or psychiatric disorder likely to interfere with his/her ability to drive a commercial motor vehicle safely. FMCSA has statutory authority to exempt individuals from certain parts of the Federal Motor Carrier Safety Regulations, if the exemptions granted will not compromise safety. The Agency must conclude that granting these exemptions provides a level of safety that will be equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers. Based on a review of the applications and following an opportunity for public comment, FMCSA has concluded that the individuals did not demonstrate that they could achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation.

DATES: This decision is effective July 24, 2015.

FOR FURTHER INFORMATION CONTACT: Charles A. Horan III, Director, Office of Carrier, Driver and Vehicle Safety Standards, (202) 366–4001, or via email at *fmcsamedical@dot.gov,* or by letter FMCSA, Room W64–224, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' FMCSA can renew exemptions at the end of each 2-year period. The three individuals listed in this notice have each requested such an exemption from the physical qualification requirements in 49 CFR 391.41(b)(8) and (b)(9), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency evaluates the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Narcolepsy is a chronic neurological disorder caused by autoimmune destruction of hypocretin-producing neurons inhibiting the brain's ability to regulate sleep-wake cycles normally. Persons with narcolepsy experience frequent excessive daytime sleepiness, comparable to how non-narcoleptics feel after 24 to 48 hours of sleep deprivation, as well as disturbed nocturnal sleep, which often is confused with insomnia. See NIH Narcolepsy Fact Sheet at *www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm.*

The Agency considered the topic of narcolepsy and the potential impact on commercial drivers in a 2009 Evidence Report. The Evidence Report ''Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle Driver Safety'' addressed several key questions.[1]

Key Question 1: Are individuals with narcolepsy (with and without cataplexy) at an increased risk for a motor vehicle crash when compared to comparable individuals without the disorder?

Key Question 2: Do currently recommended treatments for narcolepsy reduce the risk for a motor vehicle crash?

Key question 2 was further divided into several questions concerning the impact of various medication therapies for narcolepsy on driver safety. The complete report is included in the docket FMCSA 2014–0373.

The evidence report reviewed studies from the available literature and evaluated outcomes on measures of Excessive Daytime Sleepiness (EDS), cataplexy, event rate, measures of cognitive and psychomotor function, and driving performance. For key question 1, the currently available evidence (both direct and indirect) supports the contention that drivers with narcolepsy are at an increased risk for a motor vehicle crash when compared to otherwise similar individuals who do not have the disorder. The strength of the evidence was rated as strong. The direct evidence (from three crash studies) (study quality rating of ''Low'') conducted with non-CMV drivers showed that individuals with narcolepsy are at an increased risk for a crash compared to individuals who do not have narcolepsy. The indirect evidence (studies of driving tests and driving simulation, quality rating ''moderate''), examined factors associated with simulated driving outcomes, (driving performance, tracking error, fewer correct responses and more instances of going out of bounds compared to healthy controls). In summary, while there are limitations in the quality of the studies that examined direct crash risk in the evidence base, all study results showed a strong effect size and statistical significance. Indirect evidence of crash provides strong support for the direct crash study findings. Based upon available information, there is strong evidence that non-commercial drivers with narcolepsy are at an increased risk of crash.

Concerning key question 2 and its sub-questions, the American Academy of Sleep Medicine (AASM) and the European Federation of Neurological Societies recommend modafinil as the first-line of treatment and

[1] Evidence Report: Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle Driver Safety; October 6, 2009.

methylphenidate as the second-line of treatment. The AASM also recommends amphetamine, methamphetamine, or dextroamphetamine as alternative second-line treatments. No studies that directly examined the impact of treatment with modafinil, armodafinil, sodium oxybate (used with narcolepsy with cataplexy), or anti-depressants on crash risk or driving performance were identified during the literature searches. Evidence-based conclusions pertaining to treatment with these medications on crash risk and driving performance could not be drawn.

Currently available evidence suggests that amphetamines and/or methylphenidate are effective in improving symptoms of EDS in individuals with narcolepsy (quality of studies range from ''moderate to low''). However, these improvements do not result in levels of daytime sleepiness that can be considered to be normal in the vast majority of individuals. Evidence-based conclusions pertaining to the impact of treatment with amphetamines, methylphenidate, or other related stimulant drugs on cognitive and psychomotor function among individuals with narcolepsy cannot be drawn at this time.

In January 2010, the FMCSA's Medical Review Board (MRB) recommended that individuals with narcolepsy be ineligible for a commercial driver's license, even with treatment.[2]

Discussion of Public Comments

The FMCSA published the names of three individuals seeking exemption in a **Federal Register** Notice, on April 17, 2015, and requested public comment. The public comment period closed on May 18, 2015. A total of 17 commenters responded. The majority of commenters were in favor of the applicants continuing to drive CMV's with Narcolepsy. Fourteen commenters consisting mainly of private citizens stated that the individual drivers listed in the notice were responsible drivers, were stable and compliant with their medication therapy, had safe driving histories, and believed that the individuals would continue to be safe drivers while on medication The State of New York's medical consultants reviewed the docket and suggested that drivers with narcolepsy be allowed to operate commercially only if they have been treated medically and have been event-free for at least one year. Three commenters did not support exemption for drivers with narcolepsy. One anonymous commenter encouraged the FMCSA not to grant exemptions to these individuals due to concerns of the high risk of the underlying medical condition in combination with operating a large CMV.

FMCSA Response

To evaluate the effects of these exemption requests on safety, FMCSA reviewed and considered the content of each request individually and all comments received.

FMCSA acknowledges comments received attesting that individual applicants are responsible drivers currently on a stable therapeutic regimen which includes medication therapy. The Agency considered available medical and scientific data concerning medication therapy for narcolepsy. As discussed in the background section of this notice, evidence-based conclusions pertaining to treatment with medications on crash risk and driving performance could not be drawn.

Concerning ATAs comments recommending granting fewer exemptions and revising the current medical standards, FMCSA acknowledges ATA's concerns. The FMCSA has statutory authority (49 U.S.C. 31136(e) and 31315), to consider granting exemptions from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The FMCSA reviews its medical standards through the use of evidence reports, various medical expert panels and the Agency's Medical Review Board and proposes evidence-based revisions to the medical standards through the rulemaking process which takes a considerable length of time.

The exemption process is the Agency's most viable alternative in the short term to consider whether drivers with disqualifying medical conditions and who are found to meet an equivalent level of safety, should be permitted to operate in interstate commerce.

Conclusion

FMCSA evaluated the three individual exemption requests on their merits and available data from FMCSA's Evidence Reports, the Medical Review Board recommendations and public comments received. The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting the exemptions would achieve a level of safety equivalent to or greater than the level of safety maintained without the exemption. Each applicant has, prior to this notice, received a letter of final disposition on his/her exemption request. Those decision letters outlined fully the basis for the denial and constitute final Agency action. The list published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

The following three applicants are denied exemptions from the physical qualification standards in [49 CFR 391.41(b)(8)] and [49 CFR 391.41(b)(9)]: Thomas Skagen, Charles Larry Peterson, and Stanley Jandreau.

Issued on: August 3, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–20187 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–EX–P

[2] Medical Review Board Meeting; January 6, 2010; *http://www.mrb.fmcsa.dot.gov/documents/Final_Jan_6_2010_MRB_Meeting_Summary.pdf.*

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2000–8398; FMCSA–2003–14504; FMCSA–2005–20560; FMCSA–2009–0154; FMCSA–2009–0303; FMCSA–2011–0124]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 22 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective September 22, 2015. Comments must be received on or before September 16, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [Docket No. FMCSA–2000–8398; FMCSA–2003–14504; FMCSA–2005–20560; FMCSA–2009–0154; FMCSA–

2009–0303; FMCSA–2011–0124], using any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

• *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

• *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

II. Exemption Decision

This notice addresses 22 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 22 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:
Carl W. Adams (MN)
Michael K. Adams (OH)
Mark R. Anderson (MI)
Eleazar R. Balli (TX)
Darrell W. Bayless (TX)
Keith A. Bliss (NY)
Lloyd D. Burgess (OH)
Clifford D. Carpenter (MO)
Cecil A. Evey (ID)
Kamal A. Gaddah (OH)
Terry L. Hudgens (OH)
Eric M. Kousgaard (NE)
James F. McMahon, Jr. (NH)
Samuel A. Miller (IN)
Angelo D. Rogers (AL)
Larry T. Rogers (IL)
Ricky J. Sanderson (UT)
Marcial Soto-Rivas (OR)
Boyd D. Stamey (NC)
David C. Sybesma (ID)
Temesgn H. Teklezig (WA)
Matthew K. Tucker (MN)

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 22 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (65 FR 78256; 66 FR 16311; 68 FR 13360; 68 FR 19598; 68 FR 33570; 70 FR 12265; 70 FR 17504; 70 FR 25878; 70 FR 30997; 72 FR 11426; 72 FR 28093; 72 FR 40362; 74 FR 19270; 74 FR 20523; 74 FR 34394; 74 FR 37295; 74 FR 48343; 74 FR 60022; 75 FR 4623; 76 FR 34136; 76 FR 37173; 76 FR 53708; 76 FR 54530; 76 FR 55463; 78 FR 78477; 79 FR 53708). Each of these 22 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

IV. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2000–8398; FMCSA–2003–14504; FMCSA–2005–20560; FMCSA–2009–0154; FMCSA–2009–0303; FMCSA–2011–0124), indicate the specific section of this document to

which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, got to *http://www.regulations.gov* and put the docket number, ''FMCSA–2000–8398; FMCSA–2003–14504; FMCSA–2005–20560; FMCSA–2009–0154; FMCSA–2009–0303; FMCSA–2011–0124'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period and may change this notice based on your comments.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* and in the search box insert the docket number, ''FMCSA–2000–8398; FMCSA–2003–14504; FMCSA–2005–20560; FMCSA–2009–0154; FMCSA–2009–0303; FMCSA–2011–0124'' in the ''Keyword'' box and click ''Search.'' Next, click ''Open Docket Folder'' button choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Issued on: August 7, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–20189 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA- 2015–0066]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA).

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 54 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before September 16, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2015–0066 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 54 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b) (3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

II. Qualifications of Applicants

Joshua E. Adkins

Mr. Adkins, 65, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Adkins understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Adkins meets the

requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Rosendo R. Amador

Mr. Amador, 61, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Amador understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Amador meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Texas.

Thomas A. Ardoin

Mr. Ardoin, 52, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ardoin understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ardoin meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Louisiana.

Richard L. Arsenault

Mr. Arsenault, 59, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Arsenault understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Arsenault meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Texas.

George H. Bonney, Jr.

Mr. Bonney, 58, has had ITDM since 2005. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bonney understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bonney meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Hampshire.

Paul M. Boucher

Mr. Boucher, 46, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Boucher understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Boucher meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class E CDL from Michigan.

Tiffany C. Carvalho

Ms. Carvalho, 44, has had ITDM since 2014. Her endocrinologist examined her in 2015 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Carvalho understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Carvalho meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2015 and certified that she does not have diabetic retinopathy. She holds an operator's license from Minnesota.

Larry J. Christiansen

Mr. Christiansen, 67, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Christiansen understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Christiansen meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Cynthia J. Claunch

Ms. Claunch, 57, has had ITDM since 2013. Her endocrinologist examined her in 2015 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Claunch understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Claunch meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her ophthalmologist examined her in 2015 and certified that she does not have diabetic retinopathy. She holds a Class A CDL from New Mexico.

Stephen C. Crescentini

Mr. Crescentini, 46, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12

months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Crescentini understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Crescentini meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

John J. D'Agostino

Mr. D'Agostino, 71, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. D'Agostino understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. D'Agostino meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from New Jersey.

James R. Ditman

Mr. Ditman, 43, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ditman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ditman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

Eric D. Egan

Mr. Egan, 29, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Egan understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Egan meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Illinois.

Alva Eldridge

Mr. Eldridge, 69, has had ITDM since 2011. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Eldridge understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Eldridge meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Walter R. Elser

Mr. Elser, 65, has had ITDM since 2006. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Elser understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Elser meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Vermont.

Adam C. Exum

Mr. Exum, 21, has had ITDM since 2008. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Exum understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Exum meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Georgia.

Ryan S. Farrell

Mr. Farrell, 27, has had ITDM since 1992. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Farrell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Farrell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Massachusetts.

Patrick F. Felix

Mr. Felix, 57, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Felix understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Felix meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Gary M. Fosnaught

Mr. Fosnaught, 55, has had ITDM since 1995. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Fosnaught understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Fosnaught meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Jermaine Galle

Mr. Galle, 43, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Galle understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Galle meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Georgia.

Gary A. Gross

Mr. Gross, 66, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gross understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gross meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from South Dakota.

Terry L. Guynes

Mr. Guynes, 58, has had ITDM since 2007. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Guynes understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Guynes meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Missouri.

Colin W. Hale

Mr. Hale, 22, has had ITDM since 2006. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hale understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hale meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from New York.

Clarence Hill

Mr. Hill, 68, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hill understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hill meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New York.

Marcus Hughes

Mr. Hughes, 42, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hughes understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hughes meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Georgia.

Paul J. Lennon

Mr. Lennon, 59, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Lennon understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Lennon meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Illinois.

Michael C. Lewis

Mr. Lewis, 36, has had ITDM since 1980. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Lewis understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Lewis meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His

ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from South Dakota.

Lon A. Mingo

Mr. Mingo, 47, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mingo understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mingo meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Robert L. Moberly

Mr. Moberly, 74, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Moberly understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Moberly meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Oregon.

Jason L. Montgomery

Mr. Montgomery, 39, has had ITDM since 1979. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Montgomery understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Montgomery meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable proliferative diabetic retinopathy. He holds a Class A CDL from Washington.

John F. Mortieau

Mr. Mortieau, 65, has had ITDM since 2007. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mortieau understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mortieau meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Montana.

Alexander Musalin

Mr. Musalin, 43, has had ITDM since 1994. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Musalin understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Musalin meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Washington.

Clark E. Najac

Mr. Najac, 59, has had ITDM since 2008. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Najac understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Najac meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from New York.

Matthew S. Ness

Mr. Ness, 25, has had ITDM since 2011. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ness understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ness meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Andrew T. Oezer

Mr. Oezer, 21, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Oezer understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Oezer meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Michigan.

Vanja Pazin

Mr. Pazin, 44, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or

more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pazin understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pazin meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Oregon.

Troy A. Pearl

Mr. Pearl, 57, has had ITDM since 2000. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pearl understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pearl meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Washington.

Randell J. Pecenka

Mr. Pecenka, 30, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pecenka understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pecenka meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Iowa.

Leonard M. Radford

Mr. Radford, 67, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Radford understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Radford meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from Indiana.

Jerry J. Rava

Mr. Rava, 77, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Rava understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Rava meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from California.

Isaac E. Ridenour

Mr. Ridenour, 59, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ridenour understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ridenour meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Mexico.

William J. Rixon, Jr.

Mr. Rixon, 63, has had ITDM since 2011. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Rixon understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Rixon meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

Matias Rodriguez, Jr.

Mr. Rodriguez, 57, has had ITDM since 2001. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Rodriguez understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Rodriguez meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Connecticut.

William J. Schrade

Mr. Schrade, 62, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Schrade understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Schrade meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Connecticut.

John W. Schwirian

Mr. Schwirian, 57, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that

he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Schwirian understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Schwirian meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Shain L. Simpson

Mr. Simpson, 47, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Simpson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Simpson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Utah.

Neil E. Smith

Mr. Smith, 27, has had ITDM since 2000. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Smith understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Smith meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Timothy R. Sobczynski

Mr. Sobczynski, 50, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Sobczynski understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Sobczynski meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Joey F. Starnes

Mr. Starnes, 26, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Starnes understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Starnes meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Alabama.

Joshua R. Stieb

Mr. Stieb, 22, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Stieb understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Stieb meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Colorado.

Donald L. Strand

Mr. Strand, 74, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Strand understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Strand meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Montana.

Rick L. Vosburg

Mr. Vosburg, 61, has had ITDM since 2009. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Vosburg understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Vosburg meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from California.

William G. Wressell

Mr. Wressell, 69, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wressell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wressell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that

he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

Randy P. Young

Mr. Young, 49, has had ITDM since 2005. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Young understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Young meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Indiana.

III. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).[1] The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 U.S.C. 31136(e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

IV. Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2015–0066 and click the search button. When the new screen appears, click on the blue ''Comment Now!'' button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

V. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2015–0066 and click ''Search.'' Next, click ''Open Docket Folder'' and you will find all documents and comments related to the proposed rulemaking.

Issued on: August 7, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–20186 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–EX–P

[1] Section 4129(a) refers to the 2003 notice as a ''final rule.'' However, the 2003 notice did not issue a ''final rule'' but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 1235X]

MCM Rail Services LLC, d/b/a Baltimore Industrial Railroad—Petition for Discontinuance of Service Exemption—in Baltimore County, Md.

On July 28, 2015, MCM Rail Services LLC, d/b/a Baltimore Industrial Railroad (MCM Rail) filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to discontinue rail service over an approximately 12-mile line of railroad in Sparrows Point, Baltimore County, Md. (the Line). MCM Rail states that there are no mileposts on the Line. The Line is the entire system operated by MCM Rail. The Line traverses through United States Postal Service Zip Code 21219, and there are no stations on the Line.

MCM Rail states that the Line is stub-ended and therefore not capable of handling overhead traffic. Upon discontinuance of service by MCM Rail, rail service over the Line will be provided by the owner of the Line, Sparrows Point Rail, LLC (formerly known as Hilco SP Rail LLC). To MCM Rail's knowledge, the Line does not contain federally granted rights-of-way.

Because this is the discontinuance of the entire system operated by MCM Rail, no labor conditions will be imposed. Additionally, because this is a discontinuance proceeding and not an abandonment proceeding, trail use/rail banking and public use conditions are not appropriate.

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by November 13, 2015.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) to subsidize continued rail service will be due no later than November 23, 2015, or 10 days after the service of a decision granting the petition for exemption, whichever occurs sooner. Each offer must be accompanied by a $1,600 filing fee. *See* 49 CFR 1002.2(f)(25).

All filings in response to this notice must refer to Docket AB 1235X and must be sent to: (1) Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001; and (2) John K. Fiorilla, Esq., Capehart Scatchard, 8000 Midlantic Drive, Suite 300, Mt. Laurel, NJ 08054. Replies to the petition are due on or before September 8, 2015.

Persons seeking further information concerning discontinuance procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment and discontinuance regulations at 49 CFR pt. 1152. Questions concerning environmental issues may be directed to the Board's Office of Environmental Analysis (OEA) at (202) 245–0305.

Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV*.

Decided: August 12, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2015–20214 Filed 8–14–15; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2012–0087]

Advisory Committee for Aviation Consumer Protection

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of ninth meeting of advisory committee.

SUMMARY: This notice announces the ninth meeting of the Advisory Committee for Aviation Consumer Protection.

DATES: The ninth meeting of the advisory committee is scheduled for September 1, 2015, from 10:00 a.m. to 12:00 p.m., Eastern Time.

ADDRESSES: The meeting will be held in the Media Center (located on the lobby level of the West Building) at the U.S. Department of Transportation (DOT) headquarters, 1200 New Jersey Avenue SE., Washington, DC. Attendance is open to the public up to the room's capacity of 100 attendees. Since space is limited and access to the DOT headquarters building is controlled for security purposes, any member of the general public who plans to attend this meeting must notify the registration contact identified below no later than August 25, 2015.

FOR FURTHER INFORMATION CONTACT: To register to attend the meeting, please contact Amy Przybyla, Research Analyst, CENTRA Technology, Inc., *przybylaa@centratechnology.com;* 703–894–6962. For other information please contact Amna Arshad, Senior Attorney, Office of Aviation Enforcement and Proceedings, *amna.arshad@dot.gov;* U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC, 20590; 202–366–9342 (phone), 202–366–5944 (fax).

SUPPLEMENTARY INFORMATION: On May 24, 2012, the Secretary, as mandated by Section 411 of the FAA Modernization and Reform Act of 2012 (Pub. L. 112–95, 126 Stat. 11 (2012)), established the Advisory Committee for Aviation Consumer Protection. The committee's charter, drafted in accordance with the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2, sets forth policies for the operation of the advisory committee and is available on the Department's Web site at *http://www.facadatabase.gov/committee/charters.aspx?cid=2448&aid=47.*

The ninth meeting of the committee is scheduled to take place from 10:00 a.m. to 12:00 p.m. Eastern Time on September 1, 2015, in the Media Center at the DOT headquarters, 1200 New Jersey Avenue SE., Washington, DC 20590. The committee will discuss the recommendations submitted to it during the past three public meetings on the following subjects: Voice calls, government-imposed taxes and fees, airline mergers and consolidations, space allocated per passenger on aircraft, airline frequent flyer programs, airline change/cancellation fees, mandatory hotel resort fees, and baggage allowances, fees and interlining. The committee will also provide its preliminary recommendations to the Department which will form the basis for a report to the Secretary on improvements to existing aviation consumer protection programs. This meeting will be open to the public and comments by members of the public are invited. Attendance will necessarily be limited by the size of the meeting room (maximum 100 attendees). We ask that any member of the general public who plans to attend the ninth meeting notify the registration contact noted above no later than August 25, 2015.

Additionally, DOT will stream the event live on the Internet and provide a link to the recorded webcast for future viewing at *www.dot.gov/airconsumer/ACACP.*

Members of the public may present written comments at any time. The docket number referenced above (DOT–OST–2012–0087, available at *https://www.regulations.gov*) has been established for committee documents including any written comments that may be filed.

Persons with a disability who plan to attend the meeting and require special accommodations, such as an interpreter for the hearing impaired, should notify the registration contact noted above no later than August 25, 2015.

Notice of this meeting is being provided in accordance with the Federal Advisory Committee Act and the General Services Administration regulations covering management of Federal advisory committees. (41 CFR part 102–3.)

Issued in Washington, DC, on August 11, 2015.

Blane A. Workie,

Assistant General Counsel for Aviation Enforcement & Proceedings, U.S. Department of Transportation.

[FR Doc. 2015–20190 Filed 8–14–15; 8:45 am]

BILLING CODE 4910–9X–P

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of final action regarding technical and conforming amendments to federal sentencing guidelines effective November 1, 2015.

SUMMARY: On April 30, 2015, the Commission submitted to the Congress amendments to the sentencing guidelines and official commentary, which become effective on November 1, 2015, unless Congress acts to the contrary. Such amendments and the reasons for amendment subsequently were published in the **Federal Register**. 80 FR 25782 (May 5, 2015). The Commission has made technical and conforming amendments, set forth in this notice, to commentary provisions and policy statements related to those amendments.

DATES: The Commission has specified an effective date of November 1, 2015, for the amendments set forth in this notice.

FOR FURTHER INFORMATION CONTACT: Jeanne Doherty, Public Affairs Officer, (202) 502–4502, *jdoherty@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 sentencing 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 Congress pursuant to 28 U.S.C. 994(p) not later than the first day of May each year. Absent action of 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). *See* 28 U.S.C. § 994(p).

Unlike amendments made to sentencing guidelines, amendments to commentary and policy statements may be made at any time and are not subject to congressional review. To the extent practicable, the Commission endeavors to include amendments to commentary and policy statements in any submission of guideline amendments to Congress. Occasionally, however, the Commission determines that technical and conforming changes to commentary and policy statements are necessary. This notice sets forth technical and conforming amendments to commentary and policy statements that will become effective on November 1, 2015.

Authority: USSC Rules of Practice and Procedure 4.1.

Patti B. Saris,

Chair.

1. Amendment:

The Commentary to § 1B1.3 captioned ''Application Notes'', as amended by Amendment 1 of the amendments submitted to Congress on April 30, 2015, is further amended in Note 1 by inserting as the heading the following: ''*Sentencing Accountability and Criminal Liability.*—''.

The Commentary to § 1B1.3 captioned ''Application Notes'', as amended by Amendment 1 of the amendments submitted to Congress on April 30, 2015, is further amended by renumbering Notes 5 through 12 according to the following table:

Before amendment	After amendment
5	5(A)
11	5(B)
11(A)	5(B)(i)
11(B)	5(B)(ii)
10	5(C)
6	6(A)
7	6(B)
8	7
9	8
12	9

and by rearranging those Notes, as so renumbered, to place them in proper numerical order.

The Commentary to § 1B1.3 captioned ''Application Notes'', as so renumbered and rearranged, is further amended by inserting headings at the beginning of certain notes, as follows (with Notes referred to by their new numbers):

Note	*Heading to be inserted at the beginning*
5	*Application of Subsection (a)(2).*—
5(A)	*Relationship to Grouping of Multiple Counts.*—
5(B)	*''Same Course of Conduct or Common Scheme or Plan''.*—
5(C)	*Conduct Associated with a Prior Sentence.*—
6	*Application of Subsection (a)(3).*—
6(A)	*Definition of ''Harm''.*—
6(B)	*Risk or Danger of Harm.*—
7	*Factors Requiring Conviction under a Specific Statute.*—
8	*Partially Completed Offense.*—
9	*Solicitation, Misprision, or Accessory After the Fact.*—

The Commentary to § 2D1.1 captioned ''Application Notes'', is amended in Note 8(D), in the heading relating to Date Rape Drugs (except flunitrazipam, GHB, or ketamine), by striking ''flunitrazipam'' and inserting ''flunitrazepam''.

The Commentary to § 2K2.1 captioned ''Application Notes'', as amended by Amendment 1 of the amendments submitted to Congress on April 30, 2015, is further amended in Note 14(E) by striking ''Application Note 11'' both places such term appears and inserting ''Application Note 5(B)''.

The Commentary to § 2X3.1 captioned ''Application Notes'', as amended by Amendment 1 of the amendments submitted to Congress on April 30, 2015, is further amended in Note 1 by striking ''Application Note 12'' and inserting ''Application Note 9''.

The Commentary to § 2X4.1 captioned ''Application Notes'', as amended by Amendment 1 of the amendments submitted to Congress on April 30, 2015, is further amended in Note 1 by striking ''Application Note 12'' and inserting ''Application Note 9''.

The Commentary to § 8C2.8 captioned ''Application Notes'' is amended in Note 7 by striking the period at the end and inserting '').''.

Reason for Amendment: This amendment makes certain technical and conforming changes to commentary in the *Guidelines Manual.*

First, the amendment reorganizes the commentary to § 1B1.3 (Relevant Conduct (Factors that Determine the Guideline Range)), so that the order of the application notes better reflects the order of the guideline provisions to which they relate. The Commission had previously reorganized notes 1 and 2 into notes 1 through 4, also redesignating notes 3 through 10 as notes 5 through 12, in a recently promulgated amendment. *See* Amendment 1 of the amendments submitted by the Commission to Congress on April 30, 2015, 80 FR 25782 (May 5, 2015). This amendment further rearranges the commentary, specifically notes 5 through 12. The following table shows the renumbering of notes 5 through 12 that would result from the amendment in comparison to the current *Guidelines Manual* and the recently promulgated amendment to § 1B1.3.

2014 Guidelines Manual	*Recently Promulgated Amendment*	*Technical Amendment*
3	5	5(A)
9	11	5(B)
8	10	5(C)
4	6	6(A)
5	7	6(B)
6	8	7
7	9	8
10	12	9

The amendment also makes stylistic changes to the commentary to § 1B1.3, such as adding headings to certain application notes. To reflect the renumbering of application notes in § 1B1.3, conforming changes are also made to the commentary to §§ 2K2.1 (Unlawful Receipt, Possession, or Transportation of Firearms or Ammunition; Prohibited Transactions Involving Firearms or Ammunition), 2X3.1 (Accessory After the Fact), and 2X4.1 (Misprision of Felony).

Second, the amendment makes clerical changes to correct typographical errors in Application Note 8(D) to § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) and Application Note 7 to § 8C2.8 (Determining the Fine Within the Range (Policy Statement)).

[FR Doc. 2015–20108 Filed 8–14–15; 8:45 am]

BILLING CODE 2210–40–P

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of proposed amendment to the sentencing guidelines and commentary. Request for public comment, including public comment regarding retroactive application of the proposed amendment. Notice of public hearing.

SUMMARY: Pursuant to section 994(a), (o), and (p) of title 28, United States Code, the United States Sentencing Commission is considering promulgating an amendment to the sentencing guidelines and commentary. This notice sets forth the proposed amendment and a synopsis of the issues addressed by the amendment. This notice also sets forth a number of issues for comment, most of which are set forth together with the proposed amendment and one of which (regarding retroactive application of the proposed amendment) is set forth in the **SUPPLEMENTARY INFORMATION** portion of this notice.

The proposed amendment and issues for comment in this notice are as follows: A proposed amendment to revise the ''crime of violence'' and ''drug trafficking offense'' definitions in the career offender guideline and the illegal reentry guideline, including (A) a proposed amendment to § 4B1.2 (Definitions of Terms Used in Section 4B1.1) to delete the residual clause and revise the list of enumerated offenses in the ''crime of violence'' definition, (B) a proposed amendment to § 4B1.2 to implement an additional requirement related to the state felony classification in determining whether an offense qualifies as a felony under § 4B1.2, and (C) corresponding changes to the ''crime of violence'' and ''drug trafficking offense'' definitions in § 2L1.2 (Unlawfully Entering or Remaining in the United States) to bring them more into parallel with the definitions at § 4B1.2, and related issues for comment.

DATES: (1) Written Public Comment.—Written public comment regarding the proposed amendment and issues for comment set forth in this notice, including public comment regarding retroactive application of the proposed amendment, should be received by the Commission not later than November 12, 2015.

(2) Public Hearing.—The Commission plans to hold a public hearing regarding the proposed amendment and issues for comment set forth in this notice. Further information regarding the public hearing, including requirements for testifying and providing written testimony, as well as the location, time, and scope of the hearing, will be provided by the Commission on its Web site at *www.ussc.gov.*

ADDRESSES: Public comment should be sent to the Commission by electronic mail or regular mail. The email address for public comment is *Public_Comment@ussc.gov.* The regular mail address for public comment is United States Sentencing Commission, One Columbus Circle NE., Suite 2–500, Washington, DC 20002–8002, Attention: Public Affairs.

FOR FURTHER INFORMATION CONTACT: Jeanne Doherty, Public Affairs Officer, (202) 502–4502, *jdoherty@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 submits guideline amendments to the Congress not later than the first day of May each year pursuant to 28 U.S.C. 994(p).

The proposed amendment as presented in this notice contains bracketed text to indicate a heightened interest on the Commission's part in comment and suggestions regarding alternative policy choices and on whether the proposed provision is appropriate. The Commission has also highlighted certain issues for comment and invites suggestions on how the Commission should respond to those issues.

The Commission requests public comment regarding whether, pursuant to 18 U.S.C. 3582(c)(2) and 28 U.S.C. 994(u), the proposed amendment published in this notice should be included in subsection (d) of § 1B1.10 (Reduction in Term of Imprisonment as a Result of Amended Guideline Range (Policy Statement)) as an amendment that may be applied retroactively to previously sentenced defendants. The Commission lists in § 1B1.10(d) the specific guideline amendments that the court may apply retroactively under 18 U.S.C. 3582(c)(2). The background commentary to § 1B1.10 lists the purpose of the amendment, the magnitude of the change in the guideline range made by the amendment, and the difficulty of applying the amendment retroactively to determine an amended guideline range under § 1B1.10(b) as among the factors the Commission considers in selecting the amendments included in § 1B1.10(d). To the extent practicable, public comment should address each of these factors.

Publication of a proposed amendment requires the affirmative vote of at least three voting members and is deemed to be a request for public comment on the proposed amendment. *See* Rules 2.2 and 4.4 of the Commission's Rules of Practice and Procedure. In contrast, the affirmative vote of at least four voting members is required to promulgate an amendment and submit it to Congress. *See* Rule 2.2; 28 U.S.C. 994(p).

Additional information pertaining to the proposed amendment described in this notice may be accessed through the Commission's Web site at *www.ussc.gov.*

Authority: 28 U.S.C. 994(a), (o), (p), (x); USSC Rules of Practice and Procedure, Rule 4.4.

Patti B. Saris,

Chair.

1. ''Crime of Violence'' and Related Issues

Synopsis of Proposed Amendment: This proposed amendment is a result of the Commission's multi-year study of statutory and guideline definitions relating to the nature of a defendant's prior conviction (*e.g.,* ''crime of violence,'' ''aggravated felony,'' ''violent felony,'' ''drug trafficking offense,'' and ''felony drug offense'') and the impact of such definitions on the relevant statutory and guideline provisions (*e.g.,* career offender, illegal reentry, and armed career criminal). *See* United States Sentencing Commission, ''Notice of Final Priorities,'' 79 FR 49378 (Aug. 20, 2014); ''Proposed Priorities for Amendment Cycle,'' 80 FR 36594 (June 25, 2015).

The proposed amendment is also informed by the Supreme Court's recent decision in *Johnson* v. *United States,* __U.S. __, 135 S. Ct. 2551 (2015), relating to the statutory definition of ''violent felony'' in 18 U.S.C. 924(e), which held that an increased sentence under the ''residual clause'' of that definition violates due process. As the Court explained in *Johnson,* the term ''residual clause'' refers to the closing words of the statutory definition of ''violent felony.'' Under those closing words, a crime is a ''violent felony'' if it ''*otherwise involves conduct that presents a serious potential risk of physical injury to another.*'' *See* 18 U.S.C. 924(e)(2)(B)(ii) [emphasis added].

This clause, the Court held in *Johnson,* is unconstitutionally vague. The Court's holding did not implicate other parts of the statutory definition; a crime may still qualify as a ''violent felony'' under the statute if, for example, it ''has as an element the use, attempted use, or threatened use of physical force against the person of another'' (sometimes referred to as the ''elements'' clause) or if it ''is burglary, arson, or extortion'' (sometimes referred to as the ''enumerated'' clause).

Procedure

The Commission's ordinary practice with amendments to the sentencing guidelines is to publish proposals for comment in January, hold hearings in February or March, promulgate amendments in April, and submit final amendments to Congress on or shortly before May 1, to take effect on November 1. However, the Commission's organic statute authorizes the Commission to promulgate and submit amendments at any point after the beginning of a session of Congress and to specify an effective date sooner than November 1. *See* 28 U.S.C. 994(p). Publishing this proposed amendment at this time allows for the possibility that an amendment could be promulgated and submitted to Congress earlier than May 1 and could take effect earlier than November 1.

Accordingly, the Commission anticipates that in Fall 2015 it will hold a hearing on the proposed amendment and that in January 2016 it may, if appropriate, promulgate a final amendment and submit it to Congress (to take effect earlier than November 1) or publish a revised version of this proposed amendment for an additional period of comment.

Parts of the Proposed Amendment

The proposed amendment contains several parts. The Commission is considering whether to promulgate any one or more of these parts, as they are not necessarily mutually exclusive. Issues for comment are also included.

A. Elimination of ''Crime of Violence'' Residual Clause and Related Revisions to Definition of ''Crime of Violence''

The guidelines definition of ''crime of violence'' in § 4B1.2(a) was modeled after the statutory definition of ''violent felony.'' This guidelines definition is used in determining whether a defendant is a career offender under § 4B1.1 (Career Offender), and is also used in certain other guidelines. *See, e.g.,* §§ 2K1.3 (Unlawful Receipt, Possession, or Transportation of Explosive Materials; Prohibited Transactions Involving Explosive Materials), 2K2.1 (Unlawful Receipt, Possession, or Transportation of Firearms or Ammunition; Prohibited Transactions Involving Firearms and Ammunitions), 2S1.1 (Laundering of Monetary Instruments; Engaging in Monetary Transactions in Property Derived from Unlawful Activity), 4A1.2 (Definitions and Instructions for Computing Criminal History), and 5K2.17 (Semiautomatic Firearms Capable of Accepting Large Quantity Magazine (Policy Statement)).

While the statutory definition of ''violent felony'' in section 924(e) and the guidelines definition of ''crime of violence'' in § 4B1.2 are not identical in all respects — for example, they have different ''enumerated'' clauses — their residual clauses are identical. The proposed amendment amends § 4B1.2 to delete the residual clause.

In addition, the proposed amendment amends § 4B1.2 to clarify and revise the list of ''enumerated'' offenses. While some offenses covered by the definition are listed in the guideline (such as burglary of a dwelling, arson, and extortion), many other offenses covered by the definition are listed in the commentary instead (*e.g.,* murder, kidnapping, aggravated assault, robbery). The proposed amendment makes some revisions to the list of enumerated offenses, moves all enumerated offenses to the guideline, and provides definitions for the enumerated offenses in the commentary.

B. Use of the State Felony Classification in Determining Whether an Offense Qualifies as a ''Felony'' Under § 4B1.2

Under the career offender guideline, the court must analyze both the instant offense of conviction and the defendant's prior offenses of conviction. To be a career offender, the court must find (1) that the instant offense is a felony that is a crime of violence or a controlled substance offense, and (2) that the defendant has at least two prior felony convictions of either a crime of violence or a controlled substance offense. *See* § 4B1.1(a), 4B1.2; *see also* 28 U.S.C. 994(h).

To implement the requirement that the offense be a ''felony,'' the definitions in § 4B1.2(a) and (b) specify that the instant offense (whether a ''crime of violence'' or a ''controlled substance offense'') must have been an offense under federal or state law, punishable by imprisonment for a term exceeding one year. The proposed amendment adds an additional requirement: the offense must also have been classified [at the time defendant was initially sentenced] as a felony (or comparable classification) under the laws of the jurisdiction in which the defendant was convicted. If the jurisdiction does not have a ''felony'' classification, the offense must have been given a classification comparable to a felony classification.

C. Corresponding Changes to the Illegal Reentry Guideline, § 2L1.2

The definition of ''crime of violence'' in § 4B1.2 is not the only definition of ''crime of violence'' in the guidelines. In particular, § 2L1.2 (Unlawfully Entering or Remaining in the United States) sets forth a definition of ''crime of violence'' that contains a somewhat different list of ''enumerated'' offenses and does not contain a ''residual'' clause. It also sets forth a definition of ''drug trafficking offense'' that is somewhat different from the definition of ''controlled substance offense'' in § 4B1.2.

The proposed amendment would revise the definitions of ''crime of violence'' and ''drug trafficking offense'' in § 2L1.2 to bring them more into parallel with the definitions in § 4B1.2. Under the proposed amendment, the definitions in § 2L1.2 would generally follow the definitions in § 4B1.2, as revised by Parts A and B of the proposed amendment.

Proposed Amendment:

(A) ''Crime of Violence'' in § 4B1.2

Section § 4B1.2(a) is amended by striking paragraph (2) as follows:

'' (2) is burglary of a dwelling, arson, or extortion, involves use of explosives, or otherwise involves conduct that presents a serious potential risk of physical injury to another.'';

and inserting the following:

'' (2) is murder, voluntary manslaughter, kidnapping, aggravated assault, a forcible sex offense, robbery, [burglary of a dwelling][burglary], arson, or extortion, or involves use of explosives.''.

The Commentary to § 4B1.2 captioned ''Application Notes'' is amended in Note 1 by striking the second and third undesignated paragraphs as follows:

'' 'Crime of violence' includes murder, manslaughter, kidnapping, aggravated assault, forcible sex offenses, robbery, arson, extortion, extortionate extension of credit, and burglary of a dwelling. Other offenses are included as 'crimes of violence' if (A) that offense has as an element the use, attempted use, or threatened use of physical force against the person of another, or (B) the conduct set forth (*i.e.,* expressly charged) in the count of which the defendant was convicted involved use of explosives (including any explosive material or

destructive device) or, by its nature, presented a serious potential risk of physical injury to another.

'Crime of violence' does not include the offense of unlawful possession of a firearm by a felon, unless the possession was of a firearm described in 26 U.S.C. 5845(a). Where the instant offense of conviction is the unlawful possession of a firearm by a felon, § 2K2.1 (Unlawful Receipt, Possession, or Transportation of Firearms or Ammunition; Prohibited Transactions Involving Firearms or Ammunition) provides an increase in offense level if the defendant had one or more prior felony convictions for a crime of violence or controlled substance offense; and, if the defendant is sentenced under the provisions of 18 U.S.C. 924(e), § 4B1.4 (Armed Career Criminal) will apply.'',

and by striking the fifth undesignated paragraph as follows:

'' Unlawfully possessing a firearm described in 26 U.S.C. 5845(a) (*e.g.,* a sawed-off shotgun or sawed-off rifle, silencer, bomb, or machine gun) is a 'crime of violence'.'';

and by redesignating Notes 2 and 3 as Notes 3 and 4, respectively, and by inserting after Note 1 the following new Note 2:

''2. *Enumerated Offenses under Subsection (a).*—For purposes of subsection (a):

(A) 'Murder' is (i) the unlawful killing of a human being with malice aforethought (including killing a human being purposefully, knowingly, or recklessly under circumstances manifesting extreme indifference to the value of human life); or (ii) causing the death of a human being in the course of committing another felony offense.

(B) 'Voluntary manslaughter' is (i) the unlawful killing of a human being without malice, upon a sudden quarrel or heat of passion; or (ii) causing the death of a human being through actions intended to cause serious physical injury to another human being.

(C) 'Kidnapping' is an offense that includes at least (i) an act of restraining, removing, or confining another; (ii) an unlawful means of accomplishing that act; and (iii) at least one or more of the following aggravating factors: (I) the offense was committed for a nefarious purpose; (II) the offense substantially interfered with the victim's liberty; or (III) the offense exposed the victim to a substantial risk of bodily injury, sexual assault, or involuntary servitude.

(D) 'Aggravated assault' is (i) attempting to cause serious or substantial bodily injury to another, or causing such injury purposefully, knowingly, or recklessly; or (ii) attempting to cause, or purposefully, knowingly, or recklessly causing, bodily injury to another through use of a deadly weapon.

(E) A 'forcible sex offense' is any offense requiring a sexual act or sexual contact to which consent to the actor's conduct (i) is not given, or (ii) is not legally valid, such as where consent to the conduct is involuntary, incompetent, or coerced. The terms 'sexual act' and 'sexual contact' have the meaning given in 18 U.S.C. 2246.

(F) 'Robbery' is the misappropriation of property under circumstances involving immediate danger to the person of another.

(G) **[**'Burglary of a dwelling' is an unlawful or unprivileged entry into or remaining in a dwelling with intent to commit a **[**crime**][**felony**].] [**'Burglary' is an unlawful or unprivileged entry into or remaining in a building or other structure with intent to commit a **[**crime**][**felony**].]**

(H) 'Arson' is the intentional damaging, by fire or the use of explosives, of any building, vehicle, or other real property.

(I) 'Extortion' is obtaining something of value from another by the wrongful use of (i) force, (ii) fear of physical injury, or (iii) threat of physical injury.''.

(B) Requirement That Offense Be Classified as Felony Under State Law

Section 4B1.2 is amended in each of subsections (a) and (b) by inserting after ''a term exceeding one year'' both places such term appears the following: ''and classified **[**at the time the defendant was initially sentenced**]** as a felony (or comparable classification) under the laws of the jurisdiction in which the defendant was convicted''.

The Commentary to § 4B1.2 is amended in Note 1 in the paragraph that begins '' 'Prior felony conviction' means'' by inserting after ''a term exceeding one year'' the following: ''and classified **[**at the time the defendant was initially sentenced**]** as a felony (or comparable classification) under the laws of the jurisdiction in which the defendant was convicted''; and by striking ''regardless of whether such offense is specifically designated as a felony and''.

(C) Corresponding Revisions to § 2L1.2

The Commentary to § 2L1.2 captioned ''Application Notes'' is amended in Note 1 by striking subparagraph (B)(iii) as follows:

'' (iii) 'Crime of violence' means any of the following offenses under federal, state, or local law: murder, manslaughter, kidnapping, aggravated assault, forcible sex offenses (including where consent to the conduct is not given or is not legally valid, such as where consent to the conduct is involuntary, incompetent, or coerced), statutory rape, sexual abuse of a minor, robbery, arson, extortion, extortionate extension of credit, burglary of a dwelling, or any other offense under federal, state, or local law that has as an element the use, attempted use, or threatened use of physical force against the person of another.'',

and inserting the following:

''(iii) 'Crime of violence' has the meaning given that term in § 4B1.2(a). However, for purposes of subsection (b)(1)(E), which applies to misdemeanor crimes of violence, the requirements in § 4B1.2(a) that the offense be a felony (*i.e.,* punishable by a term more than one year and classified as a felony) do not apply.'';

in Note 2 by adding at the end as the last sentence the following: ''In addition, a crime of violence or a drug trafficking offense is a 'felony' only if it was classified **[**at the time the defendant was initially sentenced**]** as a felony (or comparable classification) under the laws of the jurisdiction in which the defendant was convicted.'';

and in Note 4(A) by striking ''any federal, state, or local offense punishable by a term of imprisonment of one year or less'' and inserting ''a federal or state offense, punishable by a term of imprisonment, that is not a 'felony' as defined in Application Note 2''.

Issues for Comment:

1. The Commission invites broad comment on the ''residual clause'' in the definition of ''crime of violence'' in § 4B1.2. Should the residual clause be eliminated, as proposed by the proposed amendment? If so, what other changes, if any, should be made to the guidelines definition of ''crime of violence''?

In the alternative, should the residual clause be revised? If so, how should it be revised? Should the Commission consider a different type of residual clause, such as the residual clause in 18 U.S.C. 16?

2. The Commission similarly invites broad comment on the list of ''enumerated'' offenses in the definition of ''crime of violence'' in § 4B1.2. Should the list of enumerated offenses be clarified and revised, as proposed by the proposed amendment? What offenses should be enumerated, and how (if at all) should they be defined?

For example, should the list of enumerated offenses be limited to common law offenses against the person? Should the list also include any

offense resulting in death or bodily injury to another if the defendant's conduct was knowing, intentional, or reckless?

Should the list of enumerated offenses include offenses where harm did not result, but could have resulted because of the risk involved? If so, what offenses should be included on the list, and how (if at all) should they be defined?

3. The Commission seeks comment on offenses against property and the extent to which they should be included in the guidelines definition of ''crime of violence.'' Statutory definitions relating to ''violent'' offenses account for property offenses in various ways. For example, the statutory definition of ''crime of violence'' in 18 U.S.C. 16 does not enumerate any specific property offenses, but its elements clause extends to offenses that have as an element the use, attempted use, or threatened use of physical force against the property of another, and its residual clause extends to offenses that involve a substantial risk of physical force against the property of another. In contrast, the statutory definition of ''violent felony'' in 18 U.S.C. 924(e) enumerates arson and burglary, but its elements clause and residual clause do not extend to property offenses. How, if at all, should the guidelines definition of ''crime of violence'' apply to property offenses?

4. The proposed amendment seeks comment on the enumerated offense definitions, as set forth in Part A of the proposed amendment. The definitions were derived from broad contemporary, generic definitions of the elements for the listed offenses. The Commission seeks comment generally on whether providing definitions for enumerated offenses is appropriate and specifically on whether the definitions provided are appropriate. Are there offenses that are covered by the proposed definitions but should not be? Are there offenses that are not covered by the proposed definitions but should be?

In addition, the Commission seeks specific comment on the following:

(A) The proposed definition of ''murder'' would include offenses in which the defendant causes the death of another in the course of committing any felony. This definition is worded more broadly than felony murder statutes in some states to minimize complexity and avoid difficulties with differing state law definition. The Commission seeks comment on whether such a definition is appropriate.

(B) The proposed definition of ''kidnapping'' attempts to capture the kinds of aggravating factors that some courts have held are present in state statutes. The Commission seeks comment on whether there are other factors that should be included as possible elements of kidnapping.

(C) The proposed definition of ''aggravated assault'' does not include as an aggravating factor that the victim has a special status, such as law enforcement, elderly, or minor. Should those type of assaults qualify as ''aggravated assault''? In particular, the Commission seeks comment on whether the definition of ''aggravated assault'' should include, as a possible alternative element, attempting to cause, or purposefully, knowingly, or recklessly causing, bodily injury to a person classified as a special victim under the statute of conviction (including public servants, minors, the elderly, pregnant women, and any other similar group).

(D) The proposed definition of ''forcible sex offense'' incorporates the definitions of ''sexual act'' and ''sexual contact'' in 18 U.S.C. 2246. Are there types of sex offenses that would be included in the definition of ''forcible sex offense'' set forth in the proposed amendment that should not be considered ''crimes of violence''? Are there types of sex offenses that would not be included under this definition, but should be? Should statutory rape be expressly included? Should it be expressly excluded?

(E) The proposed amendment defines ''robbery'' as the misappropriation of property under circumstances involving immediate danger to the person of another. The Commission seeks comment on whether this definition is adequately clear and on whether it is appropriate in scope. Are there types of offenses that would be included in the definition set forth in the proposed amendment that should not be considered ''crimes of violence''? Are there types of offenses that would not be included under this definition, but should be? For example, in some jurisdictions the elements of robbery may be established by a taking of property from a person or person's presence by fear (rather than, for example, by force or by injury). If the defendant was convicted of such a taking by fear, would it qualify as ''robbery'' as defined by the proposed amendment? In the alternative, would it qualify as ''extortion'' as defined by the proposed amendment? Should such a robbery (*i.e.,* the taking of property from a person or person's presence by fear) qualify as a crime of violence?

(F) The Supreme Court has determined that burglary under section 924(e) includes structures other than dwellings, but the Commission has included only burglaries of dwellings under the current definition of ''crime of violence'' at § 4B1.2. The Commission seeks comment on whether burglaries of buildings and other structures that are not dwellings should be included as ''crimes of violence.''

(G) Many states define ''arson'' to include burning of personal property. The proposed amendment does not include that type of arson in its definition of arson. The Commission seeks comment on whether the exclusion of such type of arson is appropriate. In those states that punish burning of personal property under arson statutes, what type of conduct is covered? Is it conduct that should be considered a crime of violence? Does it typically pose a risk of injury to a person?

(H) Extortion has been defined in case law as including non-violent threats, such as a threat to reveal embarrassing personal information. The definition of ''extortion'' in the proposed amendment requires the threat to be a ''threat of physical injury'' against the person. Similarly, extortion has been defined in case law as including fear, and the definition of ''extortion'' in the proposed amendment requires the fear to be a ''fear of physical injury.'' The Commission seeks comment on whether including these limitations in the ''extortion'' definition is appropriate.

5. Some commentators have suggested that the definition of ''crime of violence'' should not provide a list of enumerated offenses (*e.g.,* murder, voluntary manslaughter, aggravated assault), but should contain only an elements clause (*i.e.,* the use, attempted use, or threatened use of physical force against the person [or property] of another). The Commission seeks comment on whether such a single-prong approach would provide a sufficient and appropriate definition of ''crime of violence.'' If so, what should the ''elements clause'' provide?

6. The Commentary to § 4B1.2 states that ''crime of violence'' and ''controlled substance offense'' include the offenses of aiding and abetting, conspiring, and attempting to commit such offenses. The Commission seeks comment on whether the definitions of ''crime of violence'' and ''controlled substance offense'' should include attempts, conspiracies, and aiding and abetting. If so, should any limitations apply?

7. Part B of the proposed amendment would amend § 4B1.2 to revise the definition of ''felony.'' The Commission seeks comment on the advantages and disadvantages of using different definitions of ''felony'' in the guidelines. Should the Commission adopt a single definition of ''felony'' throughout the guidelines?

8. The revisions made by Part B would add a requirement that the offense have been classified as a felony under the laws of the jurisdiction in which the defendant was convicted. The Commission seeks comment on how this principle should apply to states that do not classify offenses as felonies, and to states (such as California) in which some offenses may be classified as either a felony or a misdemeanor at initial sentencing and the classification may change based on later events (such as a revocation of probation). The proposed amendment includes the parenthetical phrase ''(or comparable classification)'' and the bracketed phrase ''[at the time the defendant was initially sentenced]'' to address these situations. Do these phrases adequately address these situations? If not, how, if at all, should the Commission address these situations?

9. Part C of the proposed amendment would adopt for the illegal reentry guideline the same definition of ''crime of violence'' used in the career offender guideline. The Commission seeks comment on the advantages and disadvantages of using different definitions for these guidelines. Should the Commission have separate definitions for ''crime of violence'' in these guidelines?

10. The Commission seeks comment on whether any other guidelines that involve terms such as ''crime of violence,'' ''controlled substance offense,'' and ''drug trafficking offense'' should be revised to conform to the definitions used in the career offender guideline or the illegal reentry guideline (as revised by the proposed amendment). For example, what changes, if any, should be made to the firearms and explosives guidelines, §§ 2K2.1 and 2K1.3, to conform to the revisions made by the proposed amendment? What changes, if any, should be made to guidelines that use the term ''crime of violence'' but do not define it by reference to § 4B1.2 (such as guidelines that define it by reference to 18 U.S.C. 16)? Should the Commission revise those guidelines to promote a single definition of ''crime of violence'' (and terms such as ''controlled substance offense'') throughout the guidelines?

[FR Doc. 2015–20107 Filed 8–14–15; 8:45 am]

BILLING CODE 2210–40–P

DEPARTMENT OF VETERANS AFFAIRS

Funding Availability Under Supportive Services for Veteran Families (SSVF) Program

AGENCY: Veterans Health Administration, Department of Veterans Affairs (VA).

ACTION: Notice of funding availability (NOFA).

SUMMARY: VA is announcing the availability of funds for supportive services grants under the SSVF Program. This NOFA contains information concerning the SSVF Program, initial supportive services grant application processes, and the amount of funding available.

Funding Opportunity Title: SSVF Program.

Announcement Type: Initial.

Funding Opportunity Number: VA–SSVF–021015.

Catalog of Federal Domestic Assistance Number: 64.033, VA SSVF Program.

VA is announcing the availability of funds for supportive services grants under the SSVF Program. This NOFA contains information concerning the SSVF Program, initial supportive services grant application processes, and the amount of funding available. Awards made for supportive services grants will fund operations beginning October 1, 2015.

DATES: Applications for supportive services grants under the SSVF Program must be received by the SSVF Program Office by 4:00 p.m. Eastern Time on September 1, 2015. In the interest of fairness to all competing applicants, this deadline is firm as to date and hour, and VA will treat as ineligible for consideration any application that is received after the deadline. Applicants should take this practice into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by unanticipated delays, computer service outages, or other delivery-related problems.

ADDRESSES: *For a Copy of the Application Package:* Copies of the application can be downloaded directly from the SSVF Program Web site at: *www.va.gov/homeless/ssvf.asp.* Questions should be referred to the SSVF Program Office via email at *SSVF@va.gov.* For detailed SSVF Program information and requirements, see Section 62 of Title 38, Code of Federal Regulations (38 CFR part 62).

Submission of Application Package: Applicants are strongly encouraged to submit applications electronically following instructions found at *www.va.gov/homeless/ssvf.asp.* Alternatively applicants can mail in applications. If mailed, applicants must submit two completed, collated, hard copies of the application and two compact discs (CD) containing electronic versions of the entire application are required. Each application copy must (i) be fastened with a binder clip, and (ii) contain tabs listing the major sections of and exhibits to the application. Each CD must be labeled with the applicant's name and must contain an electronic copy of the entire application. A budget template must be attached in Excel format on the CD, but all other application materials may be attached in a PDF or other format. The application copies and CDs must be submitted to the following address: Supportive Services for Veteran Families Program Office National Center on Homelessness Among Veterans, 4100 Chester Avenue, Suite 201, Philadelphia, PA 19104. Applicants must submit two hard copies and two CDs. Applications may not be sent by facsimile (FAX). Applications must be received in the SSVF Program Office by 4:00 p.m. Eastern Time on the application deadline date. Applications must arrive as a complete package. Materials arriving separately will not be included in the application package for consideration and may result in the application being rejected.

Technical Assistance: Information regarding how to obtain technical assistance with the preparation of an initial supportive services grant application is available on the SSVF Program Web site at: *http://www.va.gov/HOMELESS/SSVF.asp.*

FOR FURTHER INFORMATION CONTACT: Mr. John Kuhn, SSVF Program Office, National Center on Homelessness Among Veterans, 4100 Chester Avenue, Suite 201, Philadelphia, PA 19104; via email at *SSVF@va.gov.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

A. *Purpose:* The SSVF Program's purpose is to provide supportive services grants to private non-profit organizations and consumer cooperatives, who will coordinate or provide supportive services to very low-income Veteran families who: (i) Are residing in permanent housing; (ii) are homeless and scheduled to become residents of permanent housing within a specified time period; or (iii) after exiting permanent housing within a specified time period, are seeking other housing that is responsive to such very

low-income Veteran family's needs and preferences.

B. *Funding Priorities:* VA is making funding available for up to four awards, not to exceed $3.5 million. Up to two awards will provide up to $3 million for services in the State of Wyoming. An award of up to $1 million will be available to provide services in western Nebraska. An award of up to $60,000 will be made available to provide services to Lake County in the State of Indiana. VA may make adjustments to proposed budgets submitted by applicants to ensure that the overall funding from this NOFA does not exceed $3.5 million.

C. *Definitions:* Part 62 of title 38, Code of Federal Regulations (38 CFR 62), contains definitions of terms used in the SSVF Program, eligibility criteria, and programmatic priorities. Respondents to this NOFA should base their proposals and applications on the requirements of part 62 as it exists today. Any parties receiving supportive services grants as a result of this NOFA will be required to comply with those requirements for the duration of their grant.

D. *Approach:* Grantees will be expected to leverage supportive services grant funds to enhance the housing stability of very low-income Veteran families who are occupying permanent housing. In doing so, grantees are required to establish relationships with local community resources. Therefore, agencies must work through coordinated partnerships built either through formal agreements or the informal working relationships commonly found amongst strong social service providers. As part of the application, under 38 CFR 62.22(e), all applicants are strongly encouraged to provide letters of support from their respective VA Network Homeless Coordinator (or their designee). In addition, applicants are strongly encouraged to provide letters of support from the Continuums of Care (CoC) where they plan to deliver services that reflect the applicant's engagement in the CoC's efforts to coordinate services. CoCs may elect to provide VA with a rank order of their support in lieu of providing individual letters of support. A CoC is a community plan to organize and deliver housing and services to meet the needs of people who are homeless as they move to stable housing and maximize self-sufficiency. It includes action steps to end homelessness and prevent a return to homelessness (CoC locations and contact information can be found at the Department of Housing and Urban Development's (HUD) Web site, *http://www.hudhre.info/index.cfm?do=viewCocMaps*). This coordination should describe the applicant's participation in the CoC's coordinated assessment efforts (coordinated assessment refers to a common process for accessing homeless assistance services including: Prevention, diversion, emergency shelter, transitional housing, rapid re-housing, supportive services and even permanent supportive housing). In addition, any applicant proposing to serve an Indian Tribal area is strongly encouraged to provide a letter of support from the relevant Indian Tribal Government. The aim of the provision of supportive services is to assist very low-income Veteran families residing in permanent housing to remain stably housed and to rapidly transition those not currently in permanent housing to stable housing. SSVF emphasizes the placement of homeless Veteran families who are described in regulation as (i) very low-income Veteran families who are homeless and scheduled to become residents of permanent housing within 90 days, and (ii) very low-income Veteran families who have exited permanent housing within the previous 90 days to seek other housing that is responsive to their needs and preferences. Accordingly, VA encourages eligible entities skilled in facilitating housing stability and experienced in operating rapid re-housing programs (*i.e.,* administering HUD's Homelessness Prevention and Rapid Re-Housing Program, HUD's Emergency Solution Grant (ESG), or other comparable Federal or community resources) to apply for supportive services grants. As a crisis intervention program, the SSVF Program is not intended to provide long-term support for participants, nor will it be able to address all of the financial and supportive services needs of participants that affect housing stability. Rather, when participants require long-term support, grantees should focus on connecting such participants to income supports, such as employment and mainstream Federal and community resources (*e.g.,* HUD–VA Supportive Housing program, HUD Housing Choice Voucher programs, McKinney-Vento funded supportive housing programs, Temporary Assistance for Needy Families (TANF), and Social Security Income/Social Security Disability Insurance (SSI/SSDI) etc.) that can provide ongoing support as required.

Assistance in obtaining or retaining permanent housing is a fundamental goal of the SSVF Program. Grantees must provide case management services in accordance with 38 CFR 62.31. Such case management should include tenant counseling, mediation with landlords and outreach to landlords.

E. *Authority:* Funding applied for under this NOFA is authorized by 38 U.S. Code (U.S.C.) 2044. VA implements the SSVF Program by regulation in 38 CFR part 62. Funds made available under this NOFA are subject to the requirements of the aforementioned regulations and other applicable laws and regulations.

F. *Requirements for the Use of Supportive Services Grant Funds:* The grantee's request for funding must be consistent with the limitations and uses of supportive services grant funds set forth in 38 CFR part 62 and this NOFA. In accordance with the regulations and this NOFA, the following requirements apply to supportive services grants awarded under this NOFA:

1. Grantees may use a maximum of 10 percent of supportive services grant funds for administrative costs identified in 38 CFR 62.70.

2. Grantees must use a minimum of 60 percent of the temporary financial assistance portion of their supportive services grant funds to serve very low-income Veteran families who qualify under 38 CFR 62.11. (NOTE: Grantees may request a waiver to decrease this minimum, as discussed in section V.B.3.a.)

3. Grantees may use a maximum of 50 percent of supportive services grant funds to provide the supportive service of temporary financial assistance paid directly to a third party on behalf of a participant for child care, emergency housing assistance, transportation, rental assistance, utility-fee payment assistance, security deposits, utility deposits, moving costs, and general housing stability assistance (which includes emergency supplies) in accordance with 38 CFR 62.33 and 38 CFR 62.34.

G. *Guidance for the Use of Supportive Services Grant Funds:* It is VA policy to support a ''Housing First'' model in addressing and ending homelessness. Housing First establishes housing stability as the primary intervention in working with homeless persons. The Housing First approach is based on research that shows that a homeless individual or household's first and primary need is to obtain stable housing, and that other issues that may affect the household can and should be addressed as housing is obtained. Research supports this approach as an effective means to end homelessness. Housing is not contingent on compliance with services; instead, participants must comply with a standard lease agreement and are provided with the services and supports

that are necessary to help them do so successfully.

Grantees must develop plans that will ensure that Veteran participants have the level of income and economic stability needed to remain in permanent housing after the conclusion of the SSVF intervention. Both employment and benefits assistance from VA and non-VA sources represent a significant underutilized source of income stability for homeless Veterans. The complexity of program rules and the stigma some associate with entitlement programs contributes to their lack of use. To this effect, grantees are encouraged to consider strategies that can lead to prompt and successful access to employment and benefits that are essential to retaining housing.

1. Consistent with the Housing First model supported by VA, grantees are expected to offer the following supportive services: Housing counseling; assisting participants in understanding leases; securing utilities; making moving arrangements; provide representative payee services concerning rent and utilities when needed; and mediation and outreach to property owners related to locating or retaining housing. Grantees may also assist participants by providing rental assistance, security or utility deposits, moving costs or emergency supplies; or using other Federal resources, such as the HUD's ESG, or supportive services grant funds subject to the limitations described in this NOFA and 38 CFR 62.34.

2. As SSVF is a short-term crisis intervention, grantees must develop plans that will produce sufficient income to sustain Veteran participants in permanent housing after the conclusion of the SSVF intervention. Grantees must ensure the availability of employment and vocational services either through the direct provision of these services or their availability through formal or informal service agreements. Agreements with Homeless Veteran Reintegration Programs funded by the U.S. Department of Labor are strongly encouraged. For participants unable to work due to disability, income must be established through available benefits programs.

3. Per 38 CFR 62.33, grantees must assist participants in obtaining public benefits. Grantees must screen all participants for eligibility for a broad range of entitlements such as TANF, Social Security, the Supplemental Nutrition Assistance Program, the Low Income Home Energy Assistance Program, the Earned Income Tax Credit, and local General Assistance programs. Grantees are expected to access the Substance Abuse and Mental Health Services Administration's SSI/SSDI Outreach, Access, and Recovery (SOAR) program either though community linkages or by training staff to deliver SOAR services. In addition, where available, grantees should access information technology tools to support case managers in their efforts to link participants to benefits.

4. Grantees are encouraged to provide, or assist participants in obtaining, legal services relevant to issues that interfere with the participants' ability to obtain or retain permanent housing. (NOTE: Legal services provided may be protected from release by the grantee or VA under attorney-client privilege; however, documentation demonstrating the provision of legal services are subject to audit and mandatory program monitoring.) Support for legal services can include paying for court filing fees to assist a participant with issues that interfere with the participant's ability to obtain or retain permanent housing or supportive services, including issues that affect the participant's employability and financial security. Grantees (in addition to employees and members of grantees) may represent participants before VA with respect to a claim for VA benefits, but only if they are recognized for that purpose pursuant to 38 U.S.C. Chapter 59. Further, the individual providing such representation must be accredited pursuant to 38 U.S.C. Chapter 59.

5. Access to mental health and addiction services are required by SSVF; however, grantees cannot fund these services directly through the SSVF grant. Therefore, applicants must demonstrate, through either formal or informal agreements, their ability to promote rapid access and engagement to mental health and addiction services for the Veteran and family members.

6. VA recognizes that extremely low-income Veterans, with incomes below 30 percent of the area median income, face greater barriers to permanent housing placement. Grantees should consider how they can support these participants.

7. When serving participants who are residing in permanent housing, it is required that the defining question to ask is: ''Would this individual or family be homeless but for this assistance?'' The grantee must use a VA approved screening tool with criteria that targets those most at-risk of homelessness. To qualify for SSVF services, a Veteran who is served under Category 1 (homeless prevention), the participants must not have sufficient resources or support networks (*e.g.,* family, friends, faith-based or other social networks), immediately available to prevent them from becoming homeless. To further qualify for services under Category 1, the grantee must document that the participant meets at least one of the following conditions:

(a) Has moved because of economic reasons two or more times during the 60 days immediately preceding the application for homelessness prevention assistance;

(b) Is living in the home of another because of economic hardship;

(c) Has been notified in writing that their right to occupy their current housing or living situation will be terminated within 21 days after the date of application for assistance;

(d) Lives in a hotel or motel and the cost of the hotel or motel stay is not paid by charitable organizations or by Federal, state, or local Government programs for low-income individuals;

(e) Is exiting a publicly funded institution or system of care (such as a health care facility, a mental health facility, or correctional institution) without a stable housing plan; or

(f) Otherwise lives in housing that has characteristics associated with instability and an increased risk of homelessness, as identified in the recipient's approved screening tool.

8. Where other funds from community resources are not readily available, grantees may choose to utilize supportive services grants, subject to the limitations described in this NOFA and in 38 CFR 62.33 and 62.34, to provide temporary financial assistance. Such assistance may, subject to the limitations in this NOFA and 38 CFR part 62, be paid directly to a third party on behalf of a participant for child care, transportation, emergency housing assistance, rental assistance, utility-fee payment assistance, security or utility deposits, moving costs and general housing stability assistance as necessary.

II. Award Information

A. *Overview:* This NOFA announces the availability of funds for supportive services grant under the SSVF Program. VA is making funding available for up to four awards, not to exceed $3.5 million. Up to two awards will provide up to $3 million for services in the state of Wyoming. An award of up to $1 million will be available to provide services in western Nebraska. An award of up to $60,000 will be made available to provide services to Lake County in the state of Indiana. VA may make adjustments to proposed budgets submitted by applicants to ensure that the overall funding from this NOFA does not exceed $3.5 million.

B. *Funding:* To be eligible for a supportive services grant offered through this NOFA, the applicant must be a current SSVF grantee that has existing operations in areas adjacent to the areas proposed for funding through this NOFA.

C. *Allocation of Funds:* Funding will be awarded under this NOFA to existing grantees for a 1 year period beginning October 1, 2015. The following requirements apply to supportive services grants awarded under this NOFA:

1. In response to this NOFA, applicants can only submit one application.

2. A single application may be submitted to serve the contiguous area of Wyoming and western Nebraska targeted in this NOFA. Should a single application be submitted, the requested amount cannot exceed $3.5 million.

3. Applicants must be existing SSVF grantees.

4. To facilitate the rapid launch of services, applicants must currently provide SSVF services to areas adjacent to one of the identified target communities specific to the award being sought.

D. *Supportive Services Grant Award Period:* Grant awards are generally made for a 1-year period, however, if a successful applicant currently has a longer award period for their adjacent SSVF grant, the new award will be combined with their existing grant and the length of this new award will match the current award period.

III. Eligibility Information

A. *Eligible Applicants:* In order to be eligible, an applicant must qualify as a private non-profit organization (section 501(c)(3) or 501(c)(19) tax exempt status is required) or a consumer cooperative as has the meaning given such term in section 202 of the Housing Act of 1959 (12 U.S.C. 1701q).

B. *Cost Sharing or Matching:* None.

IV. Application and Submission Information

A. *Address to Request Application Package:* Download directly from the SSVF Program Web site at *www.va.gov/homeless/ssvf.asp* or send a written request for an application to SSVF Program Office, National Center on Homelessness Among Veterans, 4100 Chester Avenue, Suite 201, Philadelphia, PA 19104. Any questions regarding this process should be referred to the SSVF Program Office via phone at (877) 737–0111 (toll-free number) or via email at *SSVF@va.gov.* For detailed SSVF Program information and requirements, see 38 CFR part 62.

B. *Content and Form of Application:* Applicants are strongly encouraged to submit applications electronically following instructions found at *www.va.gov/homeless/ssvf.asp.* Alternatively applicants can mail in applications. If mailed, applicants must submit two completed collated, hard copies of the application and two compact discs (CD) containing electronic versions of the entire application are required. Each application copy must (i) be fastened with a binder clip, and (ii) contain tabs listing the major sections of and exhibits to the application. Each CD must be labeled with the applicant's name and must contain an electronic copy of the entire application. A budget template must be attached in Excel format on the CD, but all other application materials may be attached in a PDF or other format.

C. *Submission Dates and Times:* Applications for supportive services grants under the SSVF Program must be received by the SSVF Program Office by 4:00 p.m. Eastern Time on September 1, 2015. Awards made for supportive services grants will fund operations beginning October 1, 2015. Applications must arrive as a complete package. Materials arriving separately will not be included in the application package for consideration and may result in the application being rejected. Additionally, in the interest of fairness to all competing applicants, this deadline is firm as to date and hour, and VA will treat as ineligible for consideration any application that is received after the deadline. Applicants should take this practice into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by unanticipated delays, computer service outages, or other delivery-related problems.

D. *Intergovernmental Review:* This section is not applicable to the SSVF Program.

E. *Funding Restrictions:* Up to $3.5 million may be awarded depending on funding availability and subject to available appropriations for initial supportive services grants to be funded under this NOFA. Applicants should fill out separate applications for each supportive services funding request. Funding will be awarded under this NOFA to existing grantees for a 1 to 3-year period beginning October 1, 2015 (as described in II.D.).

F. *Other Submission Requirements:*

1. Applicants shall apply as new applicant using the application designed for new grants.

2. Additional supportive services grant application requirements are specified in the initial application package. Submission of an incorrect or incomplete application package will result in the application being rejected during threshold review. The application packages must contain all required forms and certifications. Selections will be made based on criteria described in 38 CFR part 62 and this NOFA. Applicants and grantees will be notified of any additional information needed to confirm or clarify information provided in the application and the deadline by which to submit such information. Applicants are strongly encouraged to submit applications electronically. If mailed, applications and CDs must be submitted to the following address: SSVF Program Office, National Center on Homelessness Among Veterans, 4100 Chester Avenue, Suite 201, Philadelphia, PA 19104. Applicants must submit two hard copies and two CDs. Applications may not be sent by FAX.

V. Application Review Information

A. *Criteria:*

1. VA will only score applicants that meet the following threshold requirements:

(a) The application is filed within the time period established in the NOFA, and any additional information or documentation requested by VA under 38 CFR 62.20(c) is provided within the time frame established by VA;

(b) The application is completed in all parts;

(c) The applicant is an eligible entity;

(d) The activities for which the supportive services grant is requested are eligible for funding under this part;

(e) The applicant's proposed participants are eligible to receive supportive services under this part;

(f) The applicant agrees to comply with the requirements of this part;

(g) The applicant does not have an outstanding obligation to the Federal Government that is in arrears and does not have an overdue or unsatisfactory response to an audit; and

(h) The applicant is not in default by failing to meet the requirements for any previous Federal assistance.

2. VA will use the criteria described in 38 CFR 62 to score grantees applying for new supportive services grant:

3. VA will use the following process to select applicants to receive supportive services grants: VA will score all applicants that meet the threshold requirements set forth in 38 CFR 62.21 using the scoring criteria set forth in 38 CFR 62.22.

B. *Review and Selection Process:* VA will review all supportive services grant

applications in response to this NOFA according to the following steps:

1. Score all applications that meet the threshold requirements described in 38 CFR 62.21.

2. Rank those applications who score at least 75 cumulative points and receive at least one point under each of the categories identified for new applicants in 38 CFR 62.22, paragraphs (a), (b), (c), (d), and (e). The applications will be ranked in order from highest to lowest scores.

3. Applicants are required to spend no less than 60 percent of all budgeted temporary financial assistance on homeless participants defined in 38 CFR 62.11(a)(2) and (a)(3). Waivers to this 60 percent requirement may be requested when grantees can demonstrate significant local progress towards eliminating homelessness in the target service area. Waiver requests must include data from authoritative sources such as HUD's Annual Homeless Assessment Report, annual Point-In-Time Counts and evidence of decreased demand for emergency shelter and transitional housing. Waivers for the 60 percent requirement may also be requested for services provided to rural Indian tribal areas and other rural areas where shelter capacity is insufficient to meet local need.

VI. Award Administration Information

A. *Award Notices:* Although subject to change, the SSVF Program Office expects to announce the grant recipient in the fourth quarter of fiscal year 2015 with the grant beginning October 1, 2015. Prior to executing a funding agreement, VA will contact the applicant and make known the amount of proposed funding and verify that the applicant would still like the funding. Once VA verifies that the applicant is still seeking funding, VA will execute an agreement and make payments to the grant recipient in accordance with 38 CFR part 62 and other applicable provisions of this NOFA.

B. *Administrative and National Policy Requirements:* It is VA policy to support a ''Housing First'' model in addressing and ending homelessness. Housing First establishes housing stability as the primary intervention in working with homeless persons. The Housing First approach is based on research that shows that a homeless individual or household's first and primary need is to obtain stable housing, and that other issues that may affect the household can and should be addressed as housing is obtained. Housing is not contingent on compliance with services; instead, participants must comply with a standard lease agreement and are provided with the services and supports that are necessary to help them do so successfully. Research supports this approach as an effective means to end homelessness.

Consistent with the Housing First model supported by VA, grantees are expected to offer the following supportive services: Housing counseling; assisting participants in understanding leases; securing utilities; making moving arrangements; provide representative payee services concerning rent and utilities when needed; and mediation and outreach to property owners related to locating or retaining housing. Grantees may also assist participants by providing rental assistance, security or utility deposits, moving costs or emergency supplies, using other Federal resources, such as the ESG, or supportive services grant funds subject to the limitations described in this NOFA and 38 CFR 62.34.

As SSVF grants cannot be used to fund treatment for mental health or substance use disorders, applicants must provide evidence that they can provide access to such services to all program participants through formal and informal agreements with community providers.

C. *Reporting:* VA places great emphasis on the responsibility and accountability of grantees. As described in 38 CFR 62.63 and 62.71, VA has procedures in place to monitor supportive services provided to participants and outcomes associated with the supportive services provided under the SSVF Program. Applicants should be aware of the following:

1. Upon execution of a supportive services grant agreement with VA, grantees will have a VA regional coordinator assigned by the SSVF Program Office who will provide oversight and monitor supportive services provided to participants.

2. Grantees will be required to enter data into a Homeless Management Information System Web-based software application. This data will consist of information on the participants served and types of supportive services provided by grantees. Grantees must treat the data for activities funded by the SSVF Program separate from that of activities funded by other programs. Grantees will be required to work with their HMIS Administrators to export client-level data for activities funded by the SSVF Program to VA on at least a monthly basis.

3. VA shall complete annual monitoring evaluations of each grantee. Monitoring will also include the submittal of quarterly and annual financial and performance reports by the grantee. The grantee will be expected to demonstrate adherence to the grantee's proposed program concept, as described in the grantee's application. All grantees are subject to audits conducted by the VA Financial Services Center.

4. Grantees will be required to provide each participant with a satisfaction survey which can be submitted by the participant directly to VA, within 45 to 60 days of the participant's entry into the grantee's program and again within 30 days of such participant's pending exit from the grantee's program. In all cases there should be a minimum of 30 days between administration of the two surveys. In cases when a brief SSVF intervention results in the first survey being administered 30 days after exit, only one survey shall be provided.

5. Grantees will be assessed based on their ability to meet critical performance measures. In addition to meeting program requirements defined by the regulations and NOFA, grantees will be assessed on their ability to place participants into housing and the housing retention rates of participants served. Higher placement for homeless participants and higher housing retention rates for at-risk participants are expected for very-low income Veteran families when compared to extremely low-income Veteran families with incomes below 30 percent of the area median income.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: John Kuhn, Supportive SSVF Program Office, National Center on Homelessness Among Veterans, 4100 Chester Avenue, Suite 201, Philadelphia, PA 19104; email: *SSVF@va.gov*.

VIII. Other Information

A. *VA Goals and Objectives for Funds Awarded Under this NOFA:* In accordance with 38 CFR 62.22(b)(6), VA will evaluate an applicant's ability to meet VA goals and objectives for the SSVF Program. VA goals and objectives include the provision of supportive services designed to enhance the housing stability and independent living skills of very low-income Veteran families occupying permanent housing across geographic regions. For purposes of this NOFA, VA goals and objectives also include the provision of supportive services designed to rapidly re-house or prevent homelessness among people in the following target populations who also meet all requirements for being part of a very low-income Veteran family occupying permanent housing:

1. Veteran families earning less than 30 percent of area median income as most recently published by HUD for programs under section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f) (*http://www.huduser.org*).

2. Veterans with at least one dependent family member.

3. Veterans returning from Operation Enduring Freedom, Operation Iraqi Freedom, or Operation New Dawn.

B. *Payments of Supportive Services Grant Funds:* Grantees will receive payments electronically through the U.S. Department of Health and Human Services Payment Management System. Grantees will have the ability to request payments as frequently as they choose subject to the following limitations:

1. During the first quarter of the grantee's supportive services annualized grant award period, the grantee's cumulative requests for supportive services grant funds may not exceed 35 percent of the total supportive services grant award without written approval by VA.

2. By the end of the second quarter of the grantee's supportive services annualized grant award period, the grantee's cumulative requests for supportive services grant funds may not exceed 60 percent of the total supportive services grant award without written approval by VA.

3. By the end of the third quarter of the grantee's supportive services annualized grant award period, the grantee's cumulative requests for supportive services grant funds may not exceed 80 percent of the total supportive services grant award without written approval by VA.

4. By the end of the fourth quarter of the grantee's supportive services annualized grant award period, the grantee's cumulative requests for supportive services grant funds may not exceed 100 percent of the total supportive services grant award.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors II, Chief of Staff, Department of Veterans Affairs, approved this document on August 12, 2015, for publication.

Dated: August 13, 2015.

Michael Shores,

Chief Impact Analyst, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

[FR Doc. 2015–20319 Filed 8–14–15; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program; Extensions of the Medicare-Dependent, Small Rural Hospital Program and the Low-Volume Payment Adjustment for Hospitals; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1632–F and IFC]

RIN–0938–AS41

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program; Extensions of the Medicare-Dependent, Small Rural Hospital Program and the Low-Volume Payment Adjustment for Hospitals

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rule; interim final rule with comment period.

SUMMARY: We are revising 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 2016. Some of these changes implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act), the Pathway for Sustainable Growth Reform (SGR) Act of 2013, the Protecting Access to Medicare Act of 2014, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Medicare Access and CHIP Reauthorization Act of 2015, and other legislation. We also are addressing the update of 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 2016. As an interim final rule with comment period, we are implementing the statutory extensions of the Medicare-dependent, small rural hospital (MDH) Program and changes to the payment adjustment for low-volume hospitals under the IPPS.

We also are updating 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 2016 and implementing certain statutory changes to the LTCH PPS under the Affordable Care Act and the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 and the Protecting Access to Medicare Act of 2014.

In addition, we are establishing new requirements or revising existing requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) that are participating in Medicare, including related provisions for eligible hospitals and critical access hospitals participating in the Medicare Electronic Health Record (EHR) Incentive Program. We also are updating policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

DATES: *Effective Date:* This final rule is effective on October 1, 2015.

Applicability Date: The provisions of the interim final rule with comment period portion of this rule (presented in section IV.L. of the preamble) are applicable for discharges on or after April 1, 2015 and on or before September 30, 2017.

Comment Period: To be assured consideration, comments on the interim final rule with comment period presented in section IV.L. of this document must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 29, 2015.

ADDRESSES: In commenting, please refer to file code CMS–1632–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1632–IFC, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1632–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Ing-Jye Cheng, (410) 786–4548 and Donald Thompson, (410) 786–4487, Operating Prospective Payment, MS–DRGs, Deficit Reduction Act Hospital-Acquired Acquired Conditions—Present on Admission (DRA HAC–POA) Program, Hospital-Acquired Conditions Reduction Program, Hospital Readmission Reductions Program, Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH), Medicare-dependent, small rural hospital (MDH), and Low Volume Hospital Payment Adjustment Issues.

Michele Hudson, (410) 786–4487, 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.

Cindy Tourison, (410) 786–1093, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Pierre Yong, (410) 786–8896, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Mary Pratt, (410) 786–6867, LTCH Quality Data Reporting Issues.

Kim Spalding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

James Poyer, (410) 786–2261, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Deborah Krauss, (410) 786–5264, and Alexandra Mugge, (410) 786–4457, EHR Incentive Program Clinical Quality Measure Related Issues.

Elizabeth Myers, (410) 786–4751, EHR Incentive Program Nonclinical Quality Measure Related Issues.

Lauren Wu, (202) 690–7151, Certified EHR Technology Related Issues.

Kellie Shannon, (410) 786–0416, Simplified Cost Allocation Methodology Issues

SUPPLEMENTARY INFORMATION:

Electronic Access

Inspection of Public Comments: All public 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 public comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government 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 Web site

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, some of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables are generally only available through the Internet. The IPPS tables for this final rule are available through the Internet on the CMS Web site 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 2016 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2016 final rule are available through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1632–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Michael Treitel at (410) 786–4552.

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
ACoS American College of Surgeons
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
AJCC American Joint Committee on Cancer
ALOS Average length of stay
ALTHA Acute Long Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
AMI Acute myocardial infarction
AOA American Osteopathic Association
APR DRG All Patient Refined Diagnosis Related Group System
APRN Advanced practice registered nurse
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASCA Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASITN American Society of Interventional and Therapeutic Neuroradiology
ASPE Assistant Secretary for Planning and Evaluation [DHHS]
ATRA American Taxpayer Relief Act of 2012, Public Law 112–240
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CABG Coronary artery bypass graft [surgery]
CAH Critical access hospital
CARE [Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART CMS Abstraction & Reporting Tool
CAUTI Catheter-associated urinary tract infection
CBSAs Core-based statistical areas
CC Complication or comorbidity
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDAC [Medicare] Clinical Data Abstraction Center
CDAD *Clostridium difficile*-associated disease
CDC Center for Disease Control and Prevention
CERT Comprehensive error rate testing
CDI *Clostridium difficile* (C. difficile)
CFR Code of Federal Regulations
CLABSI Central line-associated bloodstream infection
CIPI Capital input price index
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated Metropolitan Statistical Area
COBRA Consolidated Omnibus Reconciliation Act of 1985, Public Law 99–272
COLA Cost-of-living adjustment
COPD Chronis obstructive pulmonary disease
CPI Consumer price index
CQM Clinical quality measure
CY Calendar year
DACA Data Accuracy and Completeness Acknowledgement
DPP Disproportionate patient percentage
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-related group
DSH Disproportionate share hospital
EBRT External Bean Radiotherapy
ECI Employment cost index
eCQM Electronic clinical quality measure
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
EMTALA Emergency Medical Treatment and Labor Act of 1986, Public Law 99–272
EP Eligible professional
FAH Federation of American Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FPL Federal poverty line
FQHC Federally qualified health center
FR Federal Register
FTE Full-time equivalent
FY Fiscal year
GAF Geographic Adjustment Factor

GME Graduate medical education
HAC Hospital-acquired condition
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
HCP Healthcare personnel
HCRIS Hospital Cost Report Information System
HHA Home health agency
HHS Department of Health and Human Services
HICAN Health Insurance Claims Account Number
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HIPC Health Information Policy Council
HIS Health information system
HIT Health information technology
HMO Health maintenance organization
HPMP Hospital Payment Monitoring Program
HSA Health savings account
HSCRC [Maryland] Health Services Cost Review Commission
HSRV Hospital-specific relative value
HSRVcc Hospital-specific relative value cost center
HQA Hospital Quality Alliance
HQI Hospital Quality Initiative
HwH Hospital-within-hospital
IBR Intern- and Resident-to-Bed Ratio
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR Information collection requirement
ICU Intensive care unit
IGI IHS Global Insight, Inc.
IHS Indian Health Service
IME Indirect medical education
I–O Input-Output
IOM Institute of Medicine
IPF Inpatient psychiatric facility
IPFQR Inpatient Psychiatric Facility Quality Reporting [Program]
IPPS [Acute care hospital] inpatient prospective payment system
IRF Inpatient rehabilitation facility
IQR Inpatient Quality Reporting
LAMCs Large area metropolitan counties
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
LTCH QRP Long-Term Care Hospital Quality Reporting Program
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10
MAP Measure Application Partnership
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
MDC Major diagnostic category
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File
MEI Medicare Economic Index
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MRHFP Medicare Rural Hospital Flexibility Program
MRSA Methicillin-resistant *Staphylococcus aureus*
MSA Metropolitan Statistical Area
MS–DRG Medicare severity diagnosis-related group
MS–LTC–DRG Medicare severity long-term care diagnosis-related group
MU Meaningful Use [EHR Incentive Program]
NAICS North American Industrial Classification System
NALTH National Association of Long Term Hospitals
NCD National coverage determination
NCHS National Center for Health Statistics
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NECMA New England County Metropolitan Areas
NHSN National Healthcare Safety Network
NQF National Quality Forum
NQS National Quality Strategy
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991, Public Law 104–113
NUBC National Uniform Billing Code
NVHRI National Voluntary Hospital Reporting Initiative
OACT [CMS] Office of the Actuary
OBRA 86 Omnibus Budget Reconciliation Act of 1986, Public Law 99–509
OES Occupational employment statistics
OIG Office of the Inspector General
OMB [Executive] Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPM [U.S.] Office of Personnel Management
OQR [Hospital] Outpatient Quality Reporting
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
PAC Postacute care
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PCH PPS-exempt cancer hospital
PCHQR PPS-exempt cancer hospital quality reporting
PMSAs Primary metropolitan statistical areas
POA Present on admission
PPI Producer price index
PPS Prospective payment system
PRM Provider Reimbursement Manual
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
PRTFs Psychiatric residential treatment facilities
PSF Provider-Specific File
PSI Patient safety indicator
PS&R Provider Statistical and Reimbursement [System]
PQRS Physician Quality Reporting System
QIG Quality Improvement Group [CMS]
QRDA Quality Reporting Data Architecture
RFA Regulatory Flexibility Act, Public Law 96–354
RHC Rural health clinic
RHQDAPU Reporting hospital quality data for annual payment update
RNHCI Religious nonmedical health care institution
RPL Rehabilitation psychiatric long-term care (hospital)
RRC Rural referral center
RSMR Risk-standardized mortality rate
RSRR Risk-standard readmission rate
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SCHIP State Child Health Insurance Program
SCIP Surgical Care Improvement Project
SFY State fiscal year
SGR Sustainable Growth Rate
SIC Standard Industrial Classification
SNF Skilled nursing facility
SOCs Standard occupational classifications
SOM State Operations Manual
SSI Surgical site infection
SSI Supplemental Security Income
SSO Short-stay outlier
SUD Substance use disorder
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
THA/TKA Total hip arthroplasty/Total knee arthroplasty
TMA TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90
TPS Total Performance Score
UHDDS Uniform hospital discharge data set
UMRA Unfunded Mandate Reform Act, Public Law 104–4
VBP [Hospital] Value Based Purchasing [Program]
VTE Venous thromboembolism

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This final rule makes 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 makes 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). It also makes policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs.

This interim final rule with comment period implements the provisions of the Medicare Access and CHIP Reauthorization Act of 2015 which extended the MDH Program and changes to the low-volume payment adjustment for hospitals through FY 2017.

Under various statutory authorities, we are making changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2016 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; and short-term acute care hospitals located in the 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 Public Law 106–113 and section 307(b)(1) of Public Law 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 long-term care hospitals (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(d)(4)(D) of the Act, which addresses certain hospital-acquired conditions (HACs), including infections. Section 1886(d)(4)(D) of the Act specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are complications or comorbidities (CCs) or major complications or comorbidities (MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions. Section 1886(d)(4)(D)(iii) of the Act requires that hospitals, effective with discharges occurring on or after October 1, 2007, submit information on Medicare claims specifying whether diagnoses were present on admission (POA). Section 1886(d)(4)(D)(i) of the Act specifies that effective for discharges occurring on or after October 1, 2008, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS–DRG if a selected condition is not POA.
- 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. A payment for indirect medical education (IME) is made under section 1886(d)(5)(B) of the Act.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase in payments to a subsection (d) hospital for 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 an adjustment to hospital payments for hospital-acquired conditions (HACs), or 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, which establishes the ''Hospital Readmissions Reduction Program'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain 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 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 disproportionate share hospital 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 under the age of 65 who are uninsured (minus 0.1 percentage points for FY 2014, and minus 0.2 percentage points for FY 2015 through FY 2017);

and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS with implementation beginning in FY 2016.
- Section 1206(b)(1) of the Pathway for SGR Reform Act of 2013, which further amended section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act, by retroactively reestablishing and extending the statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy under the LTCH PPS so that the policy will be in effect for 9 years (except for ''grandfathered'' hospital-within-hospitals (HwHs), which are permanently exempt from this policy); and section 1206(b)(2) (as amended by section 112(b) of Pub. L. 113–93), which together further amended section 114(d) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act to establish a new moratoria (subject to certain defined exceptions) on the development of new LTCHs and LTCH satellite facilities and a new moratorium on increases in the number of beds in existing LTCHs and LTCH satellite facilities beginning January 1, 2015 and ending on September 30, 2017; and section 1206(d), which instructs the Secretary to evaluate payments to LTCHs classified under section 1886(b)(1)(C)(iv)(II) of the Act and to adjust payment rates in FY 2015 or FY 2016 under the LTCH PPS, as appropriate, based upon the evaluation findings.
- Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206(c) of the Pathway for SGR Reform Act of 2013, which provides for the establishment, no later than October 1, 2015, of a functional status quality measure under the LTCH QRP for change in mobility among inpatients requiring ventilator support.
- Section 1899B of the Act, as added by the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act of 2014), which imposes new data reporting requirements for certain postacute care providers, including LTCHs.
- Section 1886(d)(12) of the Act, as amended by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015, which extended, through FY 2017, changes to the inpatient hospital payment adjustment for certain low-volume hospitals; and section 1886(d)(5)(G) of the Act, as amended by section 205 of the Medicare Access and CHIP Reauthorization Act of 2015, which extended, through FY 2017, the Medicare-dependent, small rural hospital (MDH) program.

2. Summary of the Major Provisions

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act (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. This adjustment represents 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.

While our actuaries estimated that a −9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in one year, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we made a −0.8 percent recoupment adjustment to the standardized amount in FY 2014 and FY 2015. For FY 2016, we are making an additional −0.8 percent recoupment adjustment to the standardized amount.

b. Reduction of Hospital Payments for Excess Readmissions

We are making changes in policies to 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. 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 FYs 2013 and 2014, these conditions are acute myocardial infarction, heart failure, and pneumonia. For FY 2014, we established additional exclusions to the three existing readmission measures (that is, the excess readmission ratio) to account for additional planned readmissions. We also established additional readmissions measures, chronic obstructive pulmonary disease (COPD), and total hip arthroplasty and total knee arthroplasty (THA/TKA), to be used in the Hospital Readmissions Reduction Program for FY 2015 and future years. We expanded the readmissions measures for FY 2017 and future years by adding a measure of patients readmitted following coronary artery bypass graft (CABG) surgery.

In this final rule, we are making a refinement to the pneumonia readmissions measure, which expands the measure cohort for the FY 2017 payment determination and subsequent years. Specifically, we are finalizing a modified version of the expanded pneumonia cohort from what we had specified in the FY 2016 IPPS/LTCH PPS proposed rule such that the modified version includes patients with a principal discharge diagnosis of pneumonia or aspiration pneumonia, and patients with a principal discharge diagnosis of sepsis with a secondary diagnosis of pneumonia coded as present on admission. However, we are not including patients with a principal discharge diagnosis of respiratory failure or patients with a principal discharge diagnosis of sepsis if they are coded as having severe sepsis as we had previously proposed. In addition, we are adopting an extraordinary circumstance exception policy that will align with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs and will allow hospitals that experience an extraordinary circumstance (such as a hurricane or flood) to request a waiver for use of data from the affected time period.

c. 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.

For FY 2016, we are adopting one additional measure beginning with the FY 2018 program year and one measure beginning with the FY 2021 program year. We also are removing two measures beginning with the FY 2018 program year. In addition, we are moving one measure to the Safety domain and removing the Clinical Care—Process subdomain and renaming the Clinical Care—Outcomes subdomain

as the Clinical Care domain. Finally, we are signaling our intent to propose in future rulemaking to expand one measure and to update the standard population data we use to calculate several measures beginning with the FY 2019 program year.

d. 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 and for subsequent program years. This 1-percent payment reduction applies to a hospital whose ranking is in the top 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. The amount of payment shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under section 1886(d) or 1814(b)(3) of the Act, as applicable.

In this final rule, we are making three changes to existing Hospital-Acquired Condition Reduction Program policies: (1) An expansion to the population covered by the central line-associated bloodstream infection (CLABSI) and catheter-associated urinary tract infection (CAUTI) measures to include patients in select nonintensive care unit sites within a hospital; (2) an adjustment to the relative contribution of each domain to the Total HAC Score which is used to determine if a hospital will receive the payment adjustment; and (3) a policy that will align with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs and will allow hospitals to request a waiver for use of data from the affected time period.

e. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs will 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 what otherwise would have been paid as Medicare DSH payments, will be paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH hospital will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSH hospitals for a given time period.

In this final rule, we are updating our estimates of the three factors used to determine uncompensated care payments for FY 2016. We are continuing to use the methodology we established in FY 2015 to calculate the uncompensated care payment amounts for merged hospitals such that we combine uncompensated care data for the hospitals that have undergone a merger in order to calculate their relative share of uncompensated care. We also are changing the time period of the data used to calculate the uncompensated care payment amounts to be distributed.

f. Changes to the LTCH PPS

Under the current LTCH PPS, all discharges are paid under the LTCH PPS standard Federal payment rate. In this final rule, we are implementing section 1206 of the Pathway for SGR Reform Act, which requires the establishment of an alternative site neutral payment rate for Medicare discharges from an LTCH that fail to meet certain statutory defined criteria, beginning with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. We include provisions regarding the application of the site neutral payment rate and the criteria for exclusion from the site neutral payment rate, as well as provisions on a number of methodological and implementation issues, such as the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, the intensive care unit (ICU) criterion, the ventilator criterion, the definition of ''immediately preceded'' by a subsection (d) hospital discharge, limitation on beneficiary charges in the context of the new site neutral payment rate, and the transitional blended payment rate methodology for FY 2016 and FY 2017.

In addition, we are making changes to address certain statutory requirements related to an LTCH's average length of stay criterion and discharge payment percentage. We also are providing technical clarifications relating to our FY 2015 implementation of the new statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities (subject to certain defined exceptions) and on bed increases in existing LTCHs and LTCH satellite facilities as well as making a technical revision to the regulations to more clearly reflect our established policies.

g. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, hospitals are required to report data on measures selected by the Secretary for the Hospital IQR Program in order to receive the full annual percentage increase in payments. In past years, we have established measures for reporting data and the process for submittal and validation of the data.

In this final rule, we are updating considerations for measure removal and retention. In addition, we are removing nine chart-abstracted measures for the FY 2018 payment determination and subsequent years: Six of these measures are ''topped-out'' (STK–01, STK–06, STK–08, VTE–1, VTE–2, and VTE–3) and two of the measures are suspended (IMM–1 and SCIP-Inf-4). However, we are retaining the electronic versions of five of the chart-abstracted measures finalized for removal.

We are refining two previously adopted measures for the FY 2018 payment determination and subsequent years. We are also adding seven new measures: Three new claims-based measures and one structural measure for the FY 2018 payment determination and subsequent years; and three new claims-based measures for the FY 2019 payment determination and subsequent years.

Further, for the FY 2018 payment determination, we are requiring hospitals to report a minimum of 4 electronic clinical quality measures. Under this modification to our proposal, no NQS domain distribution will be required. We are requiring that hospitals submit one quarter of electronic clinical quality measure data from either Q3 or Q4 of CY 2016 with a submission deadline of February 28, 2017. For the reporting of electronic clinical quality measures, hospitals may be certified either to the CEHRT 2014 or 2015 Edition, but must submit using the QRDA I format. We plan to finalize public reporting of electronic data in next year's rulemaking after the conclusion and assessment of the validation pilot. Six previously adopted measures (ED–1, ED–2, PC–01, STK–04, VTE–5, and VTE–6) must still be submitted via chart-abstraction regardless of whether they are also submitted as electronic clinical quality measures. We are also continuing our policy regarding STK–01 to clarify that

hospitals need not report the STK–01 measure as part of the STK measure set if reporting electronically, because no electronic specification existed for STK–01. Beginning with the FY 2018 payment determination, we are expanding our previously established extraordinary circumstances extensions/exemptions policy (79 FR 50277) to allow hospitals to utilize the existing Extraordinary Circumstances Exception (ECE) form to request exemptions based on hardships in reporting eCQMs.

Finally, we are modifying the existing processes for validation of chart-abstracted Hospital IQR Program data to remove one stratum.

h. Long-Term Care Quality Reporting Program (LTCH QRP)

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act to require the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). This program applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary.

The IMPACT Act of 2014 amended the Act in ways that affect the LTCH QRP. Specifically, section 2(a) of the IMPACT Act of 2014 added section 1899B of the Act, and section 2(c)(3) of the IMPACT Act of 2014 amended section 1886(m)(5) of the Act. Under section 1899B(a)(1) of the Act, the Secretary must require post-acute care (PAC) providers (defined in section 1899B(a)(2)(A) of the Act to include HHAs, SNFs, IRFs, and LTCHs) to submit standardized patient assessment data in accordance with section 1899B(b) of the Act, data on quality measures required under section 1899B(c)(1) of the Act, and data on resource use and other measures required under section 1899B(d)(1) of the Act. The Act also sets out specified application dates for each of the measures. The Secretary must specify the quality, resource use, and other measures not later than the applicable specified application date defined in section 1899B(a)(2)(E) of the Act.

In this final rule, we are establishing three previously finalized quality measures: One measure establishes the newly NQF-endorsed status of that quality measure; two other measures are for the purpose of establishing the cross-setting use of the previously finalized quality measures, in order to satisfy the IMPACT Act of 2014 requirement of adopting quality measures under the domains of skin integrity and falls with major injury. We are adopting an application of a fourth previously finalized LTCH functional status measure in order to meet the requirement of the IMPACT Act of 2014 to adopt a cross-setting measure under the domain of functional status, such as self-care or mobility. All four measures effect the FY 2018 annual payment update determination and beyond.

In addition, we will publicly report LTCH quality data beginning in fall 2016, on a CMS Web site, such as *Hospital Compare.* We will initially publicly report quality data on four quality measures.

Finally, we are lengthening our quarterly data submission deadlines from 45 days to 135 days beyond the end of each calendar year quarter beginning with quarter four (4) 2015 quality data. We are making this change in order to align with other quality reporting programs, and to allow an appropriate amount of time for LTCHs to review and correct quality data prior to the public posting of that data.

3. Summary of Costs and Benefits

• Adjustment for MS–DRG Documentation and Coding Changes. We are making a −0.8 percent recoupment adjustment to the standardized amount for FY 2016 to implement, in part, the requirement of section 631 of the ATRA that the Secretary make an adjustment totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. This recoupment adjustment represents 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.

While our actuaries estimated that a −9.3 percent recoupment adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases and the adjustment we made for FY 2014, we are making a −0.8 percent recoupment adjustment to the standardized amount in FY 2016. Taking into account the cumulative effects of this adjustment and the adjustments made in FYs 2014 and 2015, we currently estimate that approximately $5 to $6 billion would be left to recover under section 631 of the ATRA by the end of FY 2016. We have not yet addressed the specific amount of the final adjustment required under section 631 of the ATRA for FY 2017. We intend to address this adjustment in the FY 2017 IPPS rulemaking. However, we note that section 414 of the MACRA (Pub. L. 114–10), 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. The provision under section 414 of the MACRA does not impact our FY 2016 recoupment adjustment, and we will address this MACRA provision in future rulemaking.

• Changes to the Hospital Readmissions Reduction Program. We are making a refinement to the pneumonia readmissions measure, which will expand the measure cohort for the FY 2017 payment determination and subsequent years. In addition, we are adopting an extraordinary circumstance exception policy that will align with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs and will allow hospitals that experience an extraordinary circumstance (such as a hurricane or flood) to request a waiver for use of data from the affected time period. These changes will not significantly impact the program in FY 2016, but could impact future years, depending on actual experience.

Overall, in this final rule, we estimate that 2,666 hospitals will have their base operating DRG payments reduced by their proxy FY 2016 hospital-specific readmissions adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately $420 million in FY 2016, an increase of $6 million over the estimated FY 2015 savings.

• 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 2016 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 2016 program year and, therefore, the estimated amount available for value-based incentive payments for FY

2016 discharges is approximately $1.5 billion.

• Changes to the HAC Reduction Program for FY 2016. We are making three changes to existing HAC Reduction Program policies: (1) An expansion to the population covered by the central line-associated bloodstream infection (CLABSI) and catheter-associated urinary tract infection (CAUTI) measures to include patients in select nonintensive care unit sites within a hospital; (2) an adjustment to the relative contribution of each domain to the Total HAC Score that is used to determine if a hospital will receive the payment adjustment; and (3) a policy that will align with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs and will allow hospitals to request a waiver for use of data from the affected period. Hospitals in the top quartile of HAC scores will continue to have their HAC Reduction Program payment adjustment applied, as required by law. However, because 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 HAC Reduction Program changes for FY 2016, including which hospitals receive the adjustment, will depend on actual experience.

• Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care. Under section 1886(r) of the Act (as added by section 3313 of the Affordable Care Act), disproportionate share hospital 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 will receive 25 percent of the amount they previously would have received under the current 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, will be 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 2016, we are providing that the 75 percent of what otherwise would have been paid for Medicare DSH is adjusted to approximately 63.69 percent of the amount to reflect changes in the percentage of individuals that are uninsured and additional statutory adjustments. In other words, approximately 47.76 percent (the product of 75 percent and 63.69 percent) of our estimate of Medicare DSH payments prior to the application of section 3133 of the Affordable Care Act is available to make additional payments to hospitals for their relative share of the total amount of uncompensated care. We project that Medicare DSH payments and additional payments for uncompensated care made for FY 2016 will reduce payments overall by approximately 1 percent as compared to the Medicare DSH payments and uncompensated care payments distributed in FY 2015. 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 payment amount is not directly tied to a hospital's number of discharges.

• Implementation of Legislative Extensions Relating to the Payment Adjustment for Low-Volume Hospitals and the Medicare-Dependent, Small Rural Hospital Program. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) extended certain provisions relating to the payment adjustment for low-volume hospitals under section 1886(d)(12) of the Act and extended the Medicare-dependent, small rural hospital (MDH) Program. Section 204 of the MACRA extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment for IPPS hospital discharges occurring on or after April 1, 2015 through September 30, 2017. Section 205 of the MACRA extended the MDH program for IPPS hospital discharges occurring on or after April 1, 2015 through September 30, 2017. We project that IPPS payments for FY 2016 will increase by approximately $322 million as a result of the statutory extensions of certain provisions of the low-volume hospital payment adjustment and approximately $96 million for the MDH program compared to such payments in absence of these extensions.

• Update to the LTCH PPS Payment Rates and Other Payment Factors. Based on the best available data for the 419 LTCHs in our data base, we estimate that the changes to the payment rates and factors that we are presenting in the preamble and Addendum of this final rule, including the application of the new site neutral payment rate required by section 1886(m)(6)(A) of the Act, the update to the LTCH PPS standard Federal payment rate for FY 2016, and the changes to short-stay outlier and high-cost outlier payments will result in an estimated decrease in payments from FY 2015 of approximately $250 million.

• Hospital Inpatient Quality Reporting (IQR) Program. In this final rule, we are removing nine measures for the FY 2018 payment determination and subsequent years. We are adding seven measures to the Hospital IQR Program for the payment determination; four for the FY 2018 payment determination and subsequent years and three for FY 2019 payment determination and subsequent years. We also are requiring hospitals to report 4 of the 28 Hospital IQR Program electronic clinical quality measures that align with the Medicare EHR Incentive Program. We estimate that our policies for the adoption and removal of measures will result in total hospital costs of $169 million across 3,300 IPPS hospitals.

• Changes in LTCH Payments Related to the LTCH QRP Proposals. We believe that the increase in costs to LTCHs related to our LTCH QRP policies in this final rule is zero. We refer readers to sections VIII.C. of the preamble of this final rule for detailed discussion of the policies.

B. 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 provided for a new additional Medicare payment that considers the amount of uncompensated care provided by the hospital. Payment under this methodology began in FY 2014.

If the hospital is an approved teaching hospital, 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.

We note that the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10), enacted on April 16, 2015, extended the Medicare-dependent, small rural hospital (MDH) program through FY 2017. 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, through FY 2017, 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, has no 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: Rehabilitation hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; certain cancer hospitals; and short-term acute care hospitals located in Guam, the U.S. Virgin Islands, 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 rehabilitation hospitals and units (referred to as inpatient rehabilitation facilities (IRFs)), LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are now included as part of the IPPS annual update document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, certain cancer hospitals, short-term acute care hospitals located in Guam, the U.S. Virgin Islands, 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, as updated annually by the percentage increase in the IPPS operating market basket.

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 section 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, all LTCHs are paid 100 percent of the Federal rate. Section 1206(a) of Public Law 113–67 established the site neutral payment rate under the LTCH PPS. 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 will be paid for LTCH discharges at the new 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.

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)(1)(A) 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 Discussed in This Final Rule

The American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), enacted on January 2, 2013, made a number of changes that affect the IPPS. We announced changes related to certain IPPS provisions for FY 2013 in accordance with sections 605 and 606 of Public Law 112–240 in a notice that appeared in the **Federal Register** on March 7, 2013 (78 FR 14689).

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, also made a number of changes that affect the IPPS and the LTCH PPS. We implemented changes related to the low-volume hospital payment adjustment and MDH provisions for FY 2014 in accordance with sections 1105 and 1106 of Public Law 113–67 in an interim final rule with comment period that appeared in the **Federal Register** on March 18, 2014 (79 FR 15022).

The Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, also made a number of changes that affect the IPPS and LTCH PPS.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act of 2014) (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long-Term Care Quality Reporting Program (LTCH QRP).

The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) enacted on April 16, 2015, extended the MDH program and changes to the payment adjustment for low-volume hospitals through FY 2017.

1. American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240)

In this final rule, we are making policy changes to implement section 631 of the American Taxpayer Relief Act of 2012, which amended section 7(b)(1)(B) of Public Law 110–90 and requires a recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring in FY 2014 through FY 2017 to fully offset $11 billion (which represents the amount of the increase in aggregate payments from FYs 2008 through 2013 for which an adjustment was not previously applied).

2. Pathway for SGR Reform Act of 2013 (Pub. L. 113–67)

In this final rule, we are providing clarifications to prior policy changes, making new policy changes, and discussing the need for future policy changes to implement provisions under section 1206 of the Pathway for SGR Reform Act of 2013. These include:

- Section 1206(a), which provides for the establishment of patient criteria for exclusion from the new site neutral payment rate under the LTCH PPS, beginning in FY 2016.
- Section 1206(a)(3), which requires changes to the LTCH average length of stay criterion.
- Section 1206(b)(1), which further amended section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act by retroactively reestablishing, and extending, the statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy under the LTCH PPS so that the policy will be in effect for 9 years (except for grandfathered hospitals-within-hospitals (HwHs), which it permanently exempted from this policy).
- Section 1206(b)(2), which amended section 114(d) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act to establish new moratoria (subject to certain defined exceptions) on the development of new LTCHs and LTCH satellite facilities and a new moratorium on increases in the number of beds in existing LTCHs and LTCH satellite facilities.

3. Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)

In this final rule, we are clarifying or discussing our prior policy changes that implemented the following provisions (or portions of the following provisions) of the Protecting Access to Medicare Act of 2014 that are applicable to the IPPS and the LTCH PPS for FY 2016:

- Section 112, which makes certain changes to Medicare LTCH provisions, including modifications to the statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities.
- Section 212, which prohibits the Secretary from requiring implementation of ICD–10 code sets before October 1, 2015.

4. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act of 2014) (Pub. L. 113–185)

In this final rule, we are implementing portions of section 2 of the IMPACT Act of 2014, 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.

5. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

In this document, as an interim final rule with comment period, we are implementing sections 204 and 205 of the Medicare Access and CHIP Reauthorization Act of 2015, which extended the MDH program and changes to the low-volume payment adjustment for hospitals through FY 2017.

D. Issuance of Notice of Proposed Rulemaking

Earlier this year, we published a proposed rule that set forth proposed changes for the Medicare IPPS for operating costs and for capital-related costs of acute care hospitals for FY 2016. The proposed rule appeared in the **Federal Register** on April 30, 2015 (80 FR 24324). We also set forth proposed changes to payments to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, in the proposed rule, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2016.

Below is a summary of the major changes that we proposed to make.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we included—

- Proposed changes to MS–DRG classifications based on our yearly review, including a discussion of the conversion of MS–DRGs to ICD–10 and the implementation of the ICD–10–CM and ICD–10–PCS systems.
- Proposed application of the documentation and coding adjustment for FY 2016 resulting from implementation of the MS–DRG system.
- Proposed recalibrations of the MS–DRG relative weights.
- Proposed changes to hospital-acquired conditions (HACs) and a discussion of HACs, including infections, that would be subject to the statutorily required adjustment in MS–DRG payments for FY 2016.
- A discussion of the FY 2016 status of new technologies approved for add-on payments for FY 2015 and a presentation of our evaluation and analysis of the FY 2016 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 the proposed rule, we proposed revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed included the following:

- The proposed FY 2016 wage index update using wage data from cost reporting periods beginning in FY 2012.
- Calculation of the proposed occupational mix adjustment for FY 2016 based on the 2013 Occupational Mix Survey.
- Analysis and implementation of the proposed FY 2016 occupational mix adjustment to the wage index for acute care hospitals.
- Application of the rural floor, the proposed imputed rural floor, and the frontier State floor.
- Transitional wage indexes relating to the continued use of the revised OMB labor market area delineations based on 2010 Decennial Census data.
- Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications.
- The proposed out-migration adjustment to the wage index for acute care hospitals for FY 2016 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index. Beginning in FY 2016, we proposed new out-migration adjustments based on commuting patterns obtained from 2010 Decennial Census data.
- The timetable for reviewing and verifying the wage data used to compute the proposed FY 2016 hospital wage index.
- Determination of the labor-related share for the proposed FY 2016 wage index.
- Proposed changes to the 3-year average pension policy and proposed changes to the wage index timetable regarding pension cost for FY 2017 and subsequent years.
- Clarification of the allocation of pension costs for the wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs and Indirect Medical Education (IME) Costs

In section IV. of the preamble of the proposed rule, we discussed 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 the inpatient hospital updates for FY 2016, including the adjustment for hospitals that are not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act.
- The proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- The statutorily required IME adjustment factor for FY 2016.
- Proposal for determining Medicare DSH payments and the additional payments for uncompensated care for FY 2016.
- Proposed changes to the measures and payment adjustments under the Hospital Readmissions Reduction Program.
- 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 2016.
- Proposed elimination of the election by hospitals to use the simplified cost allocation methodology for Medicare cost reports.
- Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.
- Proposed changes in postacute care transfer policies as a result of proposed new MS–DRGs.
- A statement of our intent to discuss issues related to short inpatient hospital stays, long outpatient stays with observation services, and the related −0.2 percent IPPS payment adjustment in the CY 2016 hospital outpatient prospective payment system proposed rule.

4. Proposed FY 2016 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to the proposed rule, we discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2016.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of the proposed rule, we discussed proposed changes to payments to certain excluded hospitals for FY 2016.

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 2016.
- Proposals to implement section 1206(a)(1) of the Pathway for SGR Reform Act, which established the site neutral payment rate as the default means of paying for discharges in LTCH cost reporting periods beginning on or after October 1, 2015.
- Provisions to make technical clarifications regarding the moratoria on the establishment of new LTCHs and LTCH satellite facilities and on bed increases in existing LTCHs and LTCH satellite facilities that were established by section 1206(b)(2) of the Pathway for SGR Reform, as amended, as well as a

proposal to make a technical revision to the regulations to more clearly reflect our established policies.

• Proposal to revise the average length of stay criterion for LTCHs to implement section 1206(a)(3) of the Pathway for SGR Reform Act.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of the proposed rule, we addressed—

• Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full applicable percentage increase.

• 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 align the reporting and submission timelines for the electronic submission of clinical quality measures for the Medicare Electronic Health Record (EHR) Incentive Program for eligible hospitals and CAHs with the reporting and submission of timelines for the Hospital IQR Program. (We note that the proposal included in the proposed rule to establish in regulations an EHR technology certification criterion for reporting clinical quality measures is not being finalized in this final rule but will be addressed in a future rulemaking.)

8. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2016 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We also proposed to establish the threshold amounts for outlier cases. In addition, we addressed the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2016 for certain hospitals excluded from the IPPS.

9. Determining Standard Federal Payment Rates for LTCHs

In the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2016 LTCH PPS standard Federal payment rate. We proposed to establish the adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the fixed-loss amount, and the LTCH cost-to-charge ratios (CCRs) under the LTCH PPS.

10. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals, LTCHs, and PCHs.

11. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2016 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).

• Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.

• The standard Federal payment rate for hospital inpatient services furnished by LTCHs.

12. 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 2015 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 addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2015 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *http://www.medpac.gov*.

E. Public Comments Received in Response to the FY 2016 IPPS/LTCH PPS Proposed Rule

We received approximately 361 timely pieces of correspondence containing multiple comments on the FY 2016 IPPS/LTCH PPS proposed rule. We note that some of these public comments were outside of the scope of the proposed rule. These out-of-scope public comments are mentioned but not addressed with the policy responses in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading.

II. 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.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. 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), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50053 through 50055), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51485 through 51487), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53273), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50512), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49871).

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. FY 2016 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

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 percent to the national standardized amount. We provided for phasing in this −4.8 percent adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent 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 percent for FY 2008 and −0.9 percent for FY 2009, and we finalized the FY 2008 adjustment through rulemaking, effective October 1, 2007 (72 FR 66886).

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent, and we finalized that adjustment through rulemaking effective October 1, 2008 (73 FR 48447). The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, which reflected the amendments made by section 7(a) of Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment for FY 2009 was in addition to the −0.6 percent adjustment for FY 2008, yielding a combined effect of −1.5 percent.

2. Adjustment to the Average Standardized Amounts Required by Public Law 110–90

a. Prospective Adjustment Required by Section 7(b)(1)(A) of Public Law 110–90

Section 7(b)(1)(A) of Public Law 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years.

b. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Section 7(b)(1)(B) Public Law 110–90

If, based on a retroactive evaluation of claims data, the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different from the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional adjustment to the standardized amounts under section 1886(d) of the Act. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Public Law 110–90. This adjustment is in addition to making an appropriate adjustment to the standardized amounts under section 1886(d)(3)(A)(vi) of the Act as required by section 7(b)(1)(A) of Public Law 110–90. That is, these adjustments are intended to recoup (or repay, in the case of underpayments) spending in excess of (or less than) spending that would have occurred had the prospective adjustments for changes in documentation and coding applied in FY 2008 and FY 2009 matched the changes that occurred in those years. Public Law 110–90 requires that the Secretary only make these recoupment or repayment adjustments for discharges occurring during FYs 2010, 2011, and 2012.

3. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

In order to implement the requirements of section 7 of Public Law 110–90, we performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008 using the methodology first described in the FY 2009 IPPS/LTCH PPS final rule (73 FR 43768 and 43775) and later discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43768 through 43772). We performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims (75 FR 50057 through 50068). The results of the analysis for the FY 2011 IPPS/LTCH PPS proposed and final rules, and subsequent evaluations in FY 2012, supported that the 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS–DRG system. We were persuaded by both MedPAC's analysis (as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50064 through 50065)) and our own review of the methodologies recommended by various commenters that the methodology we employed to determine the required documentation and coding adjustments was sound.

As in prior years, the FY 2008, FY 2009, and FY 2010 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding

effects. Interested individuals may still order these files through the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This CMS Web page describes the file and provides directions and further detailed instructions for how to order.

Persons placing an order must send the following: a Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check (refer to the Web site for the required payment amount) to:

Mailing address if using the U.S. Postal Service: Centers for Medicare & Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520.

Mailing address if using express mail: Centers for Medicare & Medicaid Services, OFM/Division of Accounting—RDDC, 7500 Security Boulevard, C3–07–11, Baltimore, MD 21244–1850.

4. Prospective Adjustments for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Public Law 110–90

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43767 through 43777), we opted to delay the implementation of any documentation and coding adjustment until a full analysis of case-mix changes based on FY 2009 claims data could be completed. We refer readers to the FY 2010 IPPS/RY LTCH PPS final rule for a detailed description of our proposal, responses to comments, and finalized policy. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 5.4 percent. After accounting for the −0.6 percent and the −0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110–90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments. Unlike section 7(b)(1)(B) of Public Law 110–90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an ''appropriate'' adjustment. Therefore, as we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50061), we believed the law provided some discretion as to the manner in which we applied the prospective adjustment of −3.9 percent. As we discussed extensively in the FY 2011 IPPS/LTCH PPS final rule, it has been our practice to moderate payment adjustments when necessary to mitigate the effects of significant downward adjustments on hospitals, to avoid what could be widespread, disruptive effects of such adjustments on hospitals. Therefore, we stated that we believed it was appropriate to not implement the −3.9 percent prospective adjustment in FY 2011 because we finalized a −2.9 percent recoupment adjustment for that fiscal year. Accordingly, we did not propose a prospective adjustment under section 7(b)(1)(A) of Public Law 110–90 for FY 2011 (75 FR 23868 through 23870). We noted that, as a result, payments in FY 2011 (and in each future fiscal year until we implemented the requisite adjustment) would be higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51489 and 51497), we indicated that, because further delay of this prospective adjustment would result in a continued accrual of unrecoverable overpayments, it was imperative that we implement a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we implemented a −2.0 percent prospective adjustment to the standardized amount instead of the full −3.9 percent.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53276), we completed the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 by finalizing a −1.9 percent adjustment to the standardized amount for FY 2013. We stated that this adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix that occurred in FY 2008 and FY 2009. We believed that it was imperative to implement the full remaining adjustment, as any further delay would result in an overstated standardized amount in FY 2013 and any future fiscal years until a full adjustment was made.

We noted again that delaying full implementation of the prospective portion 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. These overpayments could not be recovered by CMS because section 7(b)(1)(B) of Public Law 110–90 limited recoupments to overpayments made in FY 2008 and FY 2009.

5. Recoupment or Repayment Adjustment Authorized by Section 7(b)(1)(B) of Public Law 110–90

Section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Public Law 110–90. This determination must be based on a retrospective evaluation of claims data. Our actuaries estimated that there was a 5.8 percentage point difference resulting in an increase in aggregate payments of approximately $6.9 billion. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50067), we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012 would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in payment rate adjustments over more than one year in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS final rule, we made an adjustment to the standardized amount of −2.9 percent, representing approximately one-half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. An adjustment of this magnitude allowed us to moderate the effects on hospitals in one year while simultaneously making it possible to implement the entire adjustment within the timeframe required under section 7(b)(1)(B) of Public Law 110–90 (that is, no later than FY 2012). For FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent

adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). Because these adjustments, in effect, balanced out, there was no year-to-year change in the standardized amount due to this recoupment adjustment for FY 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53276), we made a final +2.9 percent adjustment to the standardized amount, completing the recoupment portion of section 7(b)(1)(B) of Public Law 110–90. We note that with this positive adjustment, according to our estimates, all overpayments made in FY 2008 and FY 2009 have been fully recaptured with appropriate interest, and the standardized amount has been returned to the appropriate baseline.

6. Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

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 represents 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. As discussed earlier, this delay in implementation resulted in overstated payment rates in FYs 2010, 2011, and 2012. The resulting overpayments could not have been recovered under Public Law 110–90.

Similar to the adjustments authorized under section 7(b)(1)(B) of Public Law 110–90, the adjustment required under section 631 of the ATRA is a one-time recoupment of a prior overpayment, not a permanent reduction to payment rates. Therefore, we anticipated that any adjustment made to reduce payment rates in one year would eventually be offset by a single positive adjustment in FY 2018, once the necessary amount of overpayment was recovered. However, we note that section 414 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, Public Law 114–10, 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. The provision under section 414 of the MACRA does not impact our FY 2016 adjustment, and we will address this MACRA provision in future rulemaking.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), our actuaries estimate that a −9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014. It is often our practice to phase in payment rate adjustments over more than one year, in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, and after consideration of the public comments we received, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), we implemented a −0.8 percent recoupment adjustment to the standardized amount in FY 2014. We stated that if adjustments of approximately −0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, using standard inflation factors, we estimate that the entire $11 billion will be accounted for by the end of the statutory 4-year timeline. As estimates of any future adjustments are subject to slight variations in total savings, we did not provide for specific adjustments for FYs 2015, 2016, or 2017 at that time. We stated that we believed that this level of adjustment for FY 2014 was a reasonable and fair approach that satisfies the requirements of the statute while mitigating extreme annual fluctuations in payment rates.

Consistent with the approach discussed in the FY 2014 IPPS/LTCH PPS final rule for recouping the $11 billion required by section 631 of the ATRA, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49873 through 49874), we implemented an additional −0.8 percent recoupment adjustment to the standardized amount for FY 2015. We estimated that this level of adjustment, combined with leaving the −0.8 percent adjustment made for FY 2014 in place, would recover up to $2 billion in FY 2015. When combined with the approximately $1 billion adjustment made in FY 2014, we estimated that approximately $8 billion would be left to recover under section 631 of the ATRA.

Consistent with the approach discussed in the FY 2014 IPPS/LTCH PPS final rule for recouping the $11 billion required by section 631 of the ATRA, we proposed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24342) to implement a −0.8 percent recoupment adjustment to the standardized amount for FY 2016. We estimated that this level of adjustment, combined with leaving the −0.8 percent adjustments made for FY 2014 and FY 2015 in place, would recover up to $3 billion in FY 2016.

Comment: Several commenters restated their previous position, as set forth in comments submitted in response to the FY 2014 and FY 2015 IPPS/LTCH PPS proposed rules and summarized in the FY 2014 IPPS/LTCH PPS final rule, that CMS overstated the impact of documentation and coding effects for prior years. The commenters cited potential deficiencies in the CMS methodology and disagreed that the congressionally mandated adjustment is warranted. However, the majority of these commenters conceded that CMS is required by section 631 of the ATRA to recover $11 billion by FY 2017, and supported CMS' policy to phase in the adjustments over a 4-year period.

Response: We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517) for our response to the commenters' position that CMS overstated the impact of documentation and coding effects. We appreciate the commenters' acknowledgement that we are required by section 631 of the ATRA to recover $11 billion by FY 2017.

After consideration of the public comments we received, we are finalizing the proposal to make an additional −0.8 percent recoupment adjustment to the standardized amount for FY 2016. Taking into account the cumulative effects of this adjustment and the adjustments made in FYs 2014 and 2015, we currently estimate that approximately $5 to $6 billion would be left to recover under section 631 of the ATRA by the end of FY 2016. As we explained in the FY 2014 and FY 2015 IPPS/LTCH PPS final rules, estimates of any future adjustments are subject to variations in total estimated savings. Therefore, we have not yet addressed the specific amount of the final adjustment required under section 631 of the ATRA for FY 2017. We intend to address this adjustment in the FY 2017 IPPS rulemaking. As stated earlier, we also note that section 414 of the MACRA (Pub. L. 114–10), 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. The provision under section 414 of the MACRA does not impact our FY 2016 recoupment adjustment, and we will address this MACRA provision 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.

As we implemented cost-based relative weights, some public commenters raised concerns about potential bias in the weights due to ''charge compression,'' which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high-cost items and overvalue low-cost items if a single cost-to-charge ratio (CCR) is applied to items of widely varying costs in the same cost center. To address this concern, in August 2006, we awarded a contract to the Research Triangle Institute, International (RTI) to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across services within cost centers. For a detailed summary of RTI's findings, recommendations, and public comments that we received on the report, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48452 through 48453). In addition, we refer readers to RTI's July 2008 final report titled ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights'' (*http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf*).

In the FY 2009 IPPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for ''Medical Supplies Charged to Patients'' and another line for ''Implantable Devices Charged to Patients.'' We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS–DRG relative weights could result from correcting charge compression for devices and implants. In determining the items that should be reported in these respective cost centers, we adopted the commenters' recommendations that hospitals should use revenue codes established by the AHA's National Uniform Billing Committee to determine the items that should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. Accordingly, a new subscripted line for ''Implantable Devices Charged to Patients'' was created in July 2009. This new subscripted cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

As we discussed in the FY 2009 IPPS final rule (73 FR 48458) and in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527), in addition to the findings regarding implantable devices, RTI also found that the costs and charges of computed tomography (CT) scans, magnetic resonance imaging (MRI), and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and the OPPS relative weights would better estimate the costs of those services if CMS were to add standard cost centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the costs from charges on claims data. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create standard cost centers for CT scans, MRIs, and cardiac catheterization, and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS–2552–10. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a detailed discussion of the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization.) The new standard cost centers for CT scans, MRIs, and cardiac catheterization are effective for cost reporting periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

In the FY 2009 IPPS final rule (73 FR 48468), we stated that, due to what is typically a 3-year lag between the reporting of cost report data and the availability for use in ratesetting, we anticipated that we might be able to use data from the new ''Implantable Devices Charged to Patients'' cost center to develop a CCR for ''Implantable Devices Charged to Patients'' in the FY 2012 or FY 2013 IPPS rulemaking cycle. However, as noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report Form CMS 2552–10, we determined that a new CCR for ''Implantable Devices Charged to Patients'' might not be available before FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for CT scans, MRIs, and cardiac catheterization, we explained that data from any new cost centers that may be created will not be available until at least 3 years after they are first used (75 FR 50077). In preparation for the FY 2012 IPPS/LTCH PPS rulemaking, we checked the availability of data in the ''Implantable Devices Charged to Patients'' cost center on the FY 2009 cost reports, but we did not believe that there was a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we did not propose to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for ''Implantable Devices Charged to Patients'' for use in calculating the MS–DRG relative weights for FY 2012. We indicated that we would reassess the availability of data for the ''Implantable Devices Charged to Patients'' cost center for the FY 2013 IPPS/LTCH PPS rulemaking cycle and, if appropriate, we would propose to create a distinct CCR at that time.

During the development of the FY 2013 IPPS/LTCH PPS proposed and final rules, hospitals were still in the process of transitioning from the previous cost report Form CMS–2552–96 to the new cost report Form CMS–2552–10. Therefore, we were able to access only those cost reports in the FY 2010 HCRIS with fiscal year begin dates on or after October 1, 2009, and before May 1, 2010; that is, those cost reports on Form CMS–2552–96. Data from the Form CMS–2552–10 cost reports were not available because cost reports filed on the Form CMS–2552–10 were not accessible in the HCRIS. Further complicating matters was that, due to additional unforeseen technical difficulties, the corresponding information regarding charges for implantable devices on hospital claims was not yet available to us in the MedPAR file. Without the breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, we believed that we had no choice but to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices. We stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281 through 53283) that when we do have the necessary data for supplies and implantable

devices on the claims in the MedPAR file to create distinct CCRs for the respective cost centers for supplies and implantable devices, we hoped that we would also have data for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization, which could then be finalized through rulemaking. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281), we stated that, prior to proposing to create these CCRs, we would first thoroughly analyze and determine the impacts of the data, and that distinct CCRs for these new cost centers would be used in the calculation of the relative weights only if they were first finalized through rulemaking.

At the time of the development of the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27506 through 27507), we had a substantial number of hospitals completing all, or some, of these new cost centers on the FY 2011 Medicare cost reports, compared to prior years. We stated that we believed that the analytic findings described using the FY 2011 cost report data and FY 2012 claims data supported our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we saw no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in FY 2014, we proposed a policy to calculate the MS–DRG relative weights using 19 CCRs, creating distinct CCRs from cost report data for implantable devices, MRIs, CT scans, and cardiac catheterization.

We refer readers to the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27507 through 27509) and final rule (78 FR 50518 through 50523) in which we presented data analyses using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. The FY 2014 IPPS/LTCH PPS final rule also set forth our responses to public comments we received on our proposal to implement these CCRs. As explained in more detail in the FY 2014 IPPS/LTCH PPS final rule, we finalized our proposal to use 19 CCRs to calculate MS–DRG relative weights beginning in FY 2014—the then existing 15 cost centers and the 4 new CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. Therefore, beginning in FY 2014, we calculate the IPPS MS–DRG relative weights using 19 CCRs, creating distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

2. Discussion for FY 2016 and Summary of Public Comments Received in Response to Request on Nonstandard Cost Center Codes

Consistent with the policy established beginning for FY 2014, we calculated the MS–DRG relative weights for FY 2016 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 19 CCRs and the MS–DRG relative weights for FY 2016 is included in section II.H.3. of the preamble of this final rule.

In preparing to calculate the 19 national average CCRs developed from the cost reports, we reviewed the HCRIS data and noticed inconsistencies in hospitals' cost reporting and use of nonstandard cost center codes. In addition, we discovered that hospitals typically report the nonstandard codes with standard cost centers that are different from the standard cost centers to which CMS maps and ''rolls up'' each nonstandard code in compiling the HCRIS. As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24344), we are concerned that inconsistencies in hospitals' use of nonstandard codes, coupled with differences in the way hospitals and CMS map these nonstandard codes to standard lines, may have implications for the calculation of the 19 CCRs and the aspects of the IPPS that rely on the CCRs (for example, the calculation of the MS–DRG relative weights).

The Medicare cost report Form CMS–2552–10, Worksheet A, includes preprinted cost center codes that reflect the standard cost center descriptions by category (General Service, Routine, and Ancillary) used in most hospitals. Each preprinted standard cost center is assigned a unique 5-digit code. The preprinted 5-digit codes provide standardized meaning for data analysis, and are automatically coded by CMS-approved cost report software. To accommodate hospitals that have additional cost centers that are sufficiently different from the preprinted standard cost centers, CMS identified additional cost centers known as ''nonstandard'' cost centers. Each nonstandard cost center must be labeled appropriately and reported under a specific standard cost center. For example, under the standard cost center ''Electrocardiology'' with its 5-digit code of 06900, there are six nonstandard cost centers (for EKG and EEG, Electromyography, Cardiopulmonary, Stress Test, Cardiology, and Holter Monitor), each with a unique 5-digit code.

The instructions for the Medicare cost report Form CMS–2552–10 explain the purpose and requirements related to the standard and nonstandard cost centers. Specifically, in CMS Pub. 15–2, Chapter 40, Section 4013, the instructions for Worksheet A of Form CMS–2552–10 state:

''Cost center coding is a methodology for standardizing the meaning of cost center labels as used by health care providers on the Medicare cost report. Form CMS–2552–10 provides for preprinted cost center descriptions on Worksheet A. In addition, a space is provided for a cost center code. The preprinted cost center labels are automatically coded by CMS approved cost reporting software. These cost center descriptions are hereafter referred to as the standard cost centers. Additionally, nonstandard cost center descriptions have been identified through analysis of frequently used labels.

The use of this coding methodology allows providers to continue to use labels for cost centers that have meaning within the individual institution. The five digit cost center codes that are associated with each provider label in their electronic file provide standardized meaning for data analysis. You are required to compare any added or changed label to the descriptions offered on the standard or nonstandard cost center tables. A description of cost center coding and the table of cost center codes are in § 4095, Table 5.''

Section 4095 of CMS Pub. 15–2 (pages 40–805 and 40–806) further provides that: ''Both the standard and nonstandard cost center descriptions along with their cost center codes are shown on Table 5 . . . . Cost center codes may only be used in designated lines in accordance with the classification of the cost center(s), *i.e.,* lines 1 through 23 may only contain cost center codes within the general service cost center category of both standard and nonstandard coding. For example, in the general service cost center category for Operation of Plant cost, line 7 and subscripts thereof should only contain cost center codes of 00700–00719 and nonstandard cost center codes. This logic must hold true for all other cost center categories, *i.e.,* ancillary, inpatient routine, outpatient, other reimbursable, special purpose, and non- reimbursable cost centers.''

Table 5 of Section 4095, Chapter 40, of CMS Pub. 15–2 (pages 40–807 through 40–810) lists the electronic reporting specifications for each

standard cost center, its 5-digit code, and, separately, the nonstandard cost center descriptions and their 5-digit codes. While the nonstandard codes are categorized by General Service Cost Centers, Inpatient Routine Service Cost Centers, and Ancillary Service Cost Centers, among others, Table 5 does not map the nonstandard cost centers and codes to specific standard cost centers. In addition, the CMS-approved cost reporting software does not restrict the use of nonstandard codes to specific standard cost centers. Furthermore, the software does not prevent hospitals from manually entering in a name for a nonstandard cost center code that may be different from the name that CMS assigned to that nonstandard cost center code. For example, Table 5 specifies that the 5-digit code for the Ancillary Service nonstandard cost center ''Acupuncture'' is 03020. When CMS creates the HCRIS SAS files, CMS maps all codes 03020 to standard line 53, ''Anesthesiology''.[1] However, a review of the December 31, 2014 update of the FY 2013 HCRIS SAS files, from which the proposed 19 CCRs for FY 2016 were calculated, revealed that, of the 3,172 times that nonstandard code 03020 was reported by hospitals, it is called ''Acupuncture'' only 122 times. Instead, hospitals use various names for nonstandard code 03020, such as ''Cardiopulmonary,'' ''Sleep Lab,'' ''Diabetes Center,'' or ''Wound Care''.

As noted above, the Ancillary Service standard cost center for ''Anesthesiology'', line 53 of Worksheet A and subsequent worksheets of the Medicare cost report Form CMS–2552–10 (and its associated nonstandard cost center code 03020 ''Acupuncture'') is an example of a cost center that is subject to inconsistent reporting. Our review of the FY 2013 HCRIS as-submitted cost reports from which the proposed 19 CCRs for FY 2016 were calculated revealed that, regardless of the actual name hospitals assigned to nonstandard code 03020 (for example, ''Acupuncture'' or otherwise), hospitals reported this code almost 100 percent of the time on standard line 76, ''Other Ancillary,'' and never on standard line 53, ''Anesthesiology.'' Yet, as noted above, CMS (and previously HCFA, under earlier versions of the Medicare cost report), in creating the HCRIS database, has had the longstanding practice of mapping and rolling up all instances of nonstandard code 03020 to standard line 53, ''Anesthesiology,'' not to standard line 76, ''Other Ancillary. Therefore, the version of the HCRIS SAS files created by CMS, which CMS uses for ratesetting purposes, may differ somewhat from the as-submitted cost reports of hospitals because CMS moves various nonstandard cost centers based on cost center codes, not cost center descriptions, from the standard cost centers in which hospitals report them and places them in different standard cost centers based on CMS' roll-up specifications.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24345), we highlighted the discrepancy in the reporting of nonstandard code 03020 ''Acupuncture'' because the placement of nonstandard code 03020 and its related costs and charges seem to have the most significant implications for the calculation of one of the 19 CCRs, the Anesthesia CCR. As stated in section II.H.3. of the preamble of the proposed rule (80 FR 24413), the proposed FY 2016 CCR for Anesthesia was 0.108. We calculated this proposed CCR based on the December 31, 2014 update of the FY 2013 HCRIS, with the nonstandard cost center codes of 03020 through 03029 rolled up to standard line 53, ''Anesthesiology.'' That is, under the CMS' HCRIS specifications, we rolled up the following 5-digit codes to standard line 53, ''Anesthesiology'':[2] standard codes for ''Anesthesiology'' 05300 through 05329; and nonstandard codes for ''Acupuncture'' 03020 through 03029. For simulation purposes, we also created a version of the December 31, 2014 update of the FY 2013 HCRIS which retained nonstandard codes 03020 through 03029 on standard line 76, ''Other Ancillary,'' where hospitals actually reported these codes on their as-submitted FY 2013 cost reports. When all reported uses of nonstandard codes 03020 through 03029 remain on standard line 76, ''Other Ancillary,'' we calculated that the Anesthesia CCR would be 0.084 (instead of 0.108 as proposed in section II.H.3. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule). We also looked at the effect on the other 18 CCRs. In the version of HCRIS we created for simulation purposes, by keeping the nonstandard cost center codes in standard line 76, ''Other Ancillary,'' where hospitals typically report them, rather than remapping them according to CMS specifications, three other CCRs also were affected, although not quite as significantly as the Anesthesia CCR. As proposed in section II.H.3. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule, the proposed FY 2016 Cardiology CCR was 0.119. However, when all cardiology-related nonstandard codes were rolled up to standard line 76, ''Other Ancillary'', and not to standard line 69, ''Electrocardiology'' as under CMS' usual practice, the Cardiology CCR was 0.113. In addition, as proposed in section II.H.3. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule, the proposed FY 2016 Radiology CCR was 0.159. However, when all radiology-related nonstandard codes were rolled up to standard line 76, ''Other Ancillary'', and not to standard lines 54 (Radiology-Diagnostic), 55 (Radiology-Therapeutic), and 56 (Radioisotope) as under CMS' usual practice, the Radiology CCR was 0.161. Most notably, the CCR that was most impacted was the ''Other Services'' CCR. As proposed in section II.H.3. of the preamble of the FY 2016 proposed rule, the ''Other Services'' CCR was 0.367. However, if all nonstandard cost center codes remained in line 76, ''Other Ancillary'' as hospitals have reported them in their FY 2013 as-submitted cost reports, instead of CMS applying its usual practice of rolling up these lines to the applicable ''Electrocardiology'' and ''Radiology'' standard cost centers, among others, the ''Other Services'' CCR was 0.291. We note that we observed minimal or no differences in the remaining 15 CCRs, when their associated nonstandard cost centers were rolled up to their specific standard cost centers, versus being rolled up to the standard line 76, ''Other Ancillary.''

The differences in these CCRs computed from the HCRIS that was compiled by applying CMS' current rollup procedures of assigning nonstandard codes to specific standard cost centers, as compared to following hospitals' general practice of reporting nonstandard codes ''en masse'' on line 76, ''Other Ancillary,'' have implications for the aspects of the IPPS that rely on the CCRs (for example, the calculation of the MS–DRG relative weights). In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24345), we discussed that some questions arise: whether CMS' procedures for mapping and rolling up nonstandard cost centers to specific standard cost centers should be updated; whether hospital reporting practices are imprecise; or whether there is a combination of both of these

[1] To view how CMS rolls up the codes to create the HCRIS SAS files, we refer readers to *http://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospital-2010-form.html*. On this page, click on ''Hospital-2010–SAS.ZIP (SAS datasets and documentation)'', and from the zip file, choose the Excel spreadsheet ''2552–10 SAS FILE RECORD LAYOUT AND CROSSWALK TO 96.xlsx''. The second tab of this spreadsheet is ''NEW ROLLUPS'', and shows the standard and nonstandard 5-digit codes (columns B and C) that CMS rolls up to each standard line (column G).

[2] *Ibid.*

questions. CMS' rollup procedures were developed many years ago based on historical analysis of hospitals' cost reporting practices and health care services furnished. It may be that it would be appropriate for CMS to reevaluate its rollup procedures based on hospitals' more current cost reporting practices and contemporary health care services provided. However, one factor complicating the determination of the most accurate standard cost centers to which each respective nonstandard cost center should be mapped is hospitals' own inconsistent reporting practices. For example, it may be determined that CMS should no longer be mapping and rolling up nonstandard cost center ''Acupuncture'' and its associated 5-digit codes 03020 through 03029 to standard cost center line 53, ''Anesthesiology.'' However, determining which other standard line ''Acupuncture'' and its associated 5-digit codes 03020 through 03029 should be mapped to is unclear, given that, as mentioned above, out of the 3,172 times that codes 03020 through 03029 were reported in the FY 2013 HCRIS file, hospitals called these codes ''Acupuncture'' only 122 times, and instead called these codes a variety of other names (such as Cardiopulmonary, Sleep Lab, Wound Care, Diabetes Center, among others). Therefore, without being able to determine the true nature of the services that were actually provided, it is difficult to know which standard cost center to map these services. That is, the question arises as to whether the service provided was acupuncture because a hospital reported code 03020, or whether the service provided was cardiopulmonary, which was the name a hospital assigned to code 03020. Furthermore, if the service provided was in fact cardiopulmonary, then, as Table 5 of Section 4095 of CMS Pub. 15–2 indicates, the correct nonstandard code for cardiopulmonary is 03160, not 03020. A related question would be, if the hospital provided cardiopulmonary services, which are clearly related to cardiology, why did the hospital report those costs and charges on line 76, ''Other Ancillary,'' instead of subscripting standard line 69, ''Electrocardiology,'' and reporting the cardiopulmonary costs and charges there.

In summary, we stated in the FY 2016 IPPS/LTCH PPS proposed rule that we believe that the differences between the standard cost centers to which CMS assigns nonstandard codes when CMS rolls up cost report data to create the HCRIS SAS database, and the standard cost centers to which hospitals tend to assign and use nonstandard codes, coupled with the inconsistencies found in hospitals' use and naming of the nonstandard codes, have implications for the aspects of the IPPS that rely on the CCRs. For example, we have explained above and provided examples of how the CCRs used to calculate the MS–DRG relative weights could change, based on where certain nonstandard codes are reported and rolled up in the cost reports. However, before considering changes to our longstanding practices, in the proposed rule, we solicited public comments from stakeholders as to how to improve the use of nonstandard cost center codes. We indicated that one option might be for CMS to allow only certain nonstandard codes to be used with certain standard cost centers, meaning that CMS might require that the CMS-approved cost reporting software ''lock in'' those nonstandard codes with their assigned standard cost centers. For example, if a hospital wishes to subscript a standard cost center, the cost reporting software might allow the hospital to choose only from a predetermined set of nonstandard codes. Therefore, for example, if a hospital wished to report Cardiopulmonary costs and charges on its cost report, the only place that the hospital could do that under this approach would be from a drop down list of cardiology-related services on standard line 69, ''Electrocardiology,'' and not on another line (not even line 76, ''Other Ancillary''). We stated that some flexibility could be maintained, but within certain limits, in consideration of unique services that hospitals might provide.

Below we summarize the public comments that we received in response to our solicitation of comments on nonstandard cost center codes.

Comment: Several commenters expressed concern that issues related to reporting of costs and charges in the nonstandard cost centers could affect the validity of the CCRs used to develop the relative weights. The commenters requested that CMS provide more cost reporting instruction so that the accuracy and validity of the CCRs could be improved, through more detailed examples of how cost report and claims data are used for ratesetting, identifying what revenue codes and services should be associated with specific cost centers, and providing detailed instructions regarding cost allocation methods. The commenters believed that these types of actions would resolve some of the inconsistencies in hospital cost reporting. Several commenters supported more specific guidance and data processing on cost reporting and supported CMS' idea to ''lock in'' certain nonstandard codes with specific cost centers in the cost reporting softwares, but wanted to retain flexibility in terms of available options.

Commenters requested that CMS work with stakeholders through methods such as additional engagement with the provider community and convening a technical workgroup to receive stakeholder input. Several commenters requested that CMS provide sufficient advance notice when cost reporting process changes are made, noting that it would take time for hospitals to implement changes to their internal cost reporting processes. The commenters were generally supportive of efforts to improve the cost reporting process and cost estimation accuracy. One commenter stated that inconsistencies in reporting of nonstandard cost centers compound the problems the commenter raised in earlier public comments regarding allocation of capital costs and the new CCRs for MRIs and CT scans. Other commenters stated generally that the use of distinct CCRs for MRI and CT scans produces ''payment rates that lack face validity'' and recommended that CMS not finalize the use of the MRI and CT scan CCRs.

Response: We appreciate the input that stakeholders have provided in response to the request for comment on how to improve the use of nonstandard cost center codes. As discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24344 through 24346), we noticed inconsistencies in hospital cost reporting of nonstandard cost centers and were concerned about the implication that some of these discrepancies might have on the aspects of the IPPS that rely on CCRs. However, we did not propose any changes to the methodology or data sources for the FY 2016 CCRs and relative weights.

We appreciate the request that CMS provide more detailed instructions regarding appropriate cost reporting methodologies. We believe that the desire for more specific direction in how to report should be balanced by the need for flexibility in cost reporting based on each hospital's own internal charge structure. That balance also applies to cost allocation methodologies. As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50523) and in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50077 through 50079), we encouraged hospitals over the past several years to use the most precise cost reporting methods in response to the new cost report lines such as the MRI and CT scan standard

cost centers, which, in most cases, corresponded to the recommended cost allocation statistic. We believe that more precise cost allocation could mitigate concerns related to the accuracy of the MRI and CT scan CCRs. However, we recognized that hospitals have varying resources and capability for assigning costs and charges on the cost report, which is why in most cases we have allowed greater flexibility. As commenters noted, an instance in which we have specifically provided guidance was in connection with the decision to split the cost center for Medical Supplies Charged to Patients into one line for ''Medical Supplies Charged to Patients'' and another line for ''Implantable Devices Charged to Patients,'' where we listed the revenue codes for which charges would properly be associated with these two cost centers (we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48462 through 48463). For that specific change to address charge compression in the ''Medical Supplies'' cost center, the separation between the types of services associated with each cost center is more distinct and therefore more easily identifiable by revenue code, which may not be true of all nonstandard and standard cost centers. Regarding the comments stating that use of distinct CCRs for MRI and CT scans produce ''payment rates that lack face validity'' and that CMS not finalize use of the MRI and CT scan CCRs, we note that we did not make any proposals regarding the use of the MRI and CT scans in particular in the relative weights calculation for FY 2016. As we have done since FY 2014, we are using the MRI and CT scan CCRs to calculate the IPPS relative weights for FY 2016. We also note that we have previously addressed stakeholder concerns related to the CT scan and MRI standard cost centers in setting the IPPS relative weights. For a detailed discussion of the CT scan and MRI standard cost centers, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50520 through 50523), and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50077 through 50079).

We appreciate the comments that stakeholders submitted and will continue to explore ways in which we can improve the accuracy of the cost report data and calculated CCRs used in the cost estimation process. To the extent possible, we will continue to seek stakeholder input in efforts to limit the impact on providers. In the interim, while we are considering these public comments, as we proposed, we are using the 19 CCRs for FY 2016 (listed in section II.H.3. of the preamble of this final rule) that were calculated from the March 2015 update of the FY 2013 HCRIS, created in accordance with CMS' current longstanding procedures for mapping and rolling up nonstandard cost center codes. As we did with the FY 2015 IPPS/LTCH PPS final rule, we are providing the version of the HCRIS from which we calculated these 19 CCRs on the FY 2016 IPPS Final Rule Home Page at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016–IPPS-Final-Rule-Home-Page.html*.[3]

F. Adjustment to MS–DRGs for Preventable Hospital-Acquired Conditions (HACs), Including Infections for FY 2016

1. Background

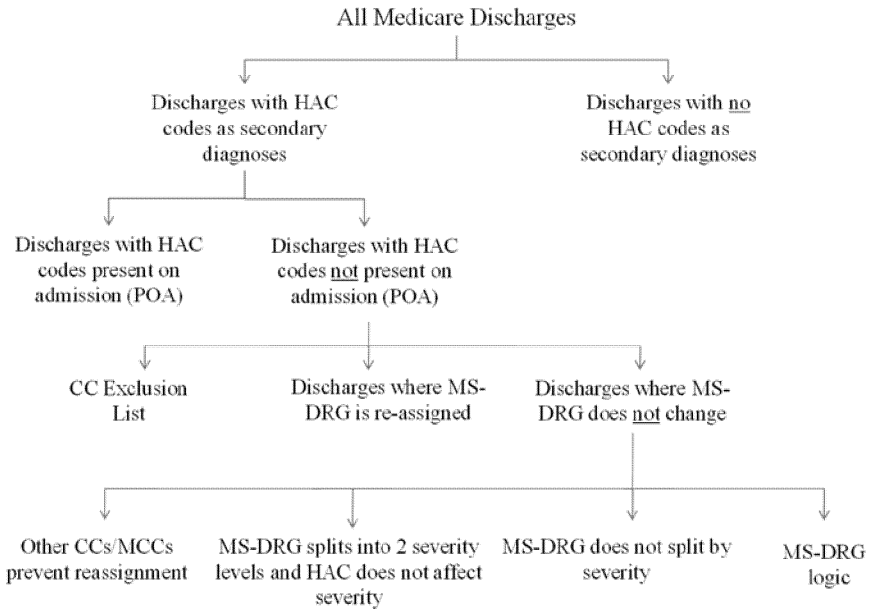
Section 1886(d)(4)(D) of the Act addresses certain hospital-acquired conditions (HACs), including infections. This provision is part of an array of Medicare tools that we are using to promote increased quality and efficiency of care. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications.

However, the treatment of these conditions can generate higher Medicare payments in two ways. First, if a hospital incurs exceptionally high costs treating a patient, the hospital stay may generate an outlier payment. However, because the outlier payment methodology requires that hospitals experience large losses on outlier cases before outlier payments are made, hospitals have an incentive to prevent outliers. Second, under the MS–DRG system that took effect in FY 2008 and that has been refined through rulemaking in subsequent years, certain conditions can generate higher payments even if the outlier payment requirements are not met. Under the MS–DRG system, there are currently 261 sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a complication or comorbidity (CC) or a major complication or comorbidity (MCC). The presence of a CC or an MCC generally results in a higher payment.

Section 1886(d)(4)(D) of the Act specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with the CDC, from time to time as long as the list contains at least two conditions.

Effective for discharges occurring on or after October 1, 2008, under the authority of section 1886(d)(4)(D) of the Act, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS–DRG if a selected condition is not present on admission (POA). Thus, if a selected condition that was not POA manifests during the hospital stay, it is considered a HAC and the case is paid as though the secondary diagnosis was not present. However, even if a HAC manifests during the hospital stay, if any nonselected CC or MCC appears on the claim, the claim will be paid at the higher MS–DRG rate. In addition, Medicare continues to assign a discharge to a higher paying MS–DRG if a selected condition is POA. When a HAC is not POA, payment can be affected in a manner shown in the diagram below.

[3] *Ibid.*



2. HAC Selection

Beginning in FY 2007, we have set forth proposals, and solicited and responded to public comments, to implement section 1886(d)(4)(D) of the Act through the IPPS annual rulemaking process. For specific policies addressed in each rulemaking cycle, including a detailed discussion of the collaborative interdepartmental process and public input regarding selected and potential candidate HACs, we refer readers to the following rules: The FY 2007 IPPS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPPS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPPS proposed rule (73 FR 23547) and final rule (73 FR 48471); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23880) and final rule (75 FR 50080); the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25810 through 25816) and final rule (76 FR 51504 through 51522); the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898) and final rule (77 FR 53283 through 53303); the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27509 through 27512) and final rule (78 FR 50523 through 50527), and the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28000 through 28003) and final rule (79 FR 49876 through 49880). A complete list of the 14 current categories of HACs is included on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html*.

3. Present on Admission (POA) Indicator Reporting

Collection of POA indicator data is necessary to identify which conditions were acquired during hospitalization for the HAC payment provision as well as for broader public health uses of Medicare data. In previous rulemaking, we provided both CMS and CDC Web site resources that are available to hospitals for assistance in this reporting effort. For detailed information regarding these sites and materials, including the application and use of POA indicators, we refer the reader to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 through 51507).

Currently, as we have discussed in the prior rulemaking cited under section II.I.2. of the preamble of this final rule, the POA indicator reporting requirement only applies to IPPS hospitals and Maryland hospitals because they are subject to this HAC provision. Non-IPPS hospitals, including CAHs, LTCHs, IRFs, IPFs, cancer hospitals, children's hospitals, RNHCIs, and the Department of Veterans Affairs/Department of Defense hospitals, are exempt from POA reporting.

There are currently four POA indicator reporting options, ''Y'', ''W'', ''N'', and ''U'', as defined by the *ICD–9–CM Official Guidelines for Coding and Reporting*. We note that prior to January 1, 2011, we also used a POA indicator reporting option ''1''. However, beginning on or after January 1, 2011, hospitals were required to begin reporting POA indicators using the 5010 electronic transmittal standards format. The 5010 format removes the need to report a POA indicator of ''1'' for codes that are exempt from POA reporting. We issued CMS instructions on this reporting change as a One-Time Notification, Pub. No. 100–20, Transmittal No. 756, Change Request 7024, effective on August 13, 2010, which can be located at the following link on the CMS Web site: *http://www.cms.gov/manuals/downloads/Pub100_20.pdf*. The current POA indicators and their descriptors are shown in the chart below:

Indicator	Descriptor
Y	Indicates that the condition was present on admission.
W	Affirms that the hospital has determined that, based on data and clinical judgment, it is not possible to document when the onset of the condition occurred.
N	Indicates that the condition was not present on admission.
U	Indicates that the documentation is insufficient to determine if the condition was present at the time of admission.

Under the HAC payment policy, we treat HACs coded with ''Y'' and ''W'' indicators as POA and allow the condition on its own to cause an increased payment at the CC and MCC level. We treat HACs coded with ''N'' and ''U'' indicators as Not Present on Admission (NPOA) and do not allow the condition on its own to cause an increased payment at the CC and MCC level. We refer readers to the following rules for a detailed discussion of POA indicator reporting: The FY 2009 IPPS proposed rule (73 FR 23559) and final rule (73 FR 48486 through 48487); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43784 through 43785); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23881 through 23882) and final rule (75 FR 50081 through 50082); the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25812 through 25813) and final rule (76 FR 51506 through 51507); the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27893 through 27894) and final rule (77 FR 53284 through 53285); the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27510 through 27511) and final rule (78 FR 50524 through 50525), and the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28001 through 28002) and final rule (79 FR 49877 through 49878).

In addition, as discussed previously in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53324), the 5010 format allows the reporting and, effective January 1, 2011, the processing of up to 25 diagnoses and 25 procedure codes. As such, it is necessary to report a valid POA indicator for each diagnosis code, including the principal diagnosis and all secondary diagnoses up to 25.

4. HACs and POA Reporting in Preparation for Transition to ICD–10–CM and ICD–10–PCS

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 and 51507), in preparation for the transition to the ICD–10–CM and ICD–10–PCS code sets, we indicated that further information regarding the use of the POA indicator with the ICD–10–CM/ICD–10–PCS classifications as they pertain to the HAC policy would be discussed in future rulemaking.

At the March 5, 2012 and the September 19, 2012 meetings of the ICD–9–CM Coordination and Maintenance Committee, an announcement was made with regard to the availability of the ICD–9–CM HAC list translation to ICD–10–CM and ICD–10–PCS code sets. Participants were informed that the list of the ICD–9–CM selected HACs had been translated into codes using the ICD–10–CM and ICD–10–PCS classification system. It was recommended that the public review this list of ICD–10–CM/ICD–10–PCS code translations of the selected HACs available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.* We encouraged the public to submit comments on these translations through the HACs Web page using the CMS ICD–10–CM/PCS HAC Translation Feedback Mailbox that was set up for this purpose under the Related Links section titled ''CMS HAC Feedback.'' We also encouraged readers to review the educational materials and draft code sets available for ICD–10–CM/PCS on the CMS Web site at: *http://www.cms.gov/ICD10/.* Lastly, we provided information regarding the ICD–10 MS–DRG Conversion Project on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html.*

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50525), we stated that the final HAC list translation from ICD–9–CM to ICD–10–CM/ICD–10–PCS would be subject to formal rulemaking. We again encouraged readers to review the educational materials and updated draft code sets available for ICD–10–CM/ICD–10–PCS on the CMS Web site at: *http://www.cms.gov/ICD10/.* In addition, we stated that the draft ICD–10–CM Coding Guidelines could be viewed on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10cm.htm.*

However, prior to engaging in rulemaking for the FY 2015 DRA HAC program, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included a new compliance date that requires the use of ICD–10 beginning October 1, 2015. The August 4, 2014 final rule is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2014-08-04/pdf/2014-18347.pdf.* That final rule also requires HIPAA covered entities to continue to use ICD–9–CM through September 30, 2015. Further information on the ICD–10 rules can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/Statute_Regulations.html.*

As described in section II.F.5. of the preamble of this final rule, we are implementing the HAC list translations from ICD–9–CM to ICD–10–CM/ICD–10–PCS in this FY 2016 IPPS/LTCH PPS final rule.

5. Changes to the HAC Program for FY 2016

As discussed in section II.G. 1. a. of the preamble of this final rule, for FY 2016, we are implementing the ICD–10 MS–DRGs Version 33 as the replacement logic for the ICD–9–CM MS–DRGs Version 32. As part of our DRA HAC update for FY 2016, we proposed to implement the ICD–10–CM/PCS Version 33 HAC list to replace the ICD–9–CM Version 32 HAC list.

CMS prepared the ICD–10 MS–DRGs Version 32 based on the FY 2015 MS–DRGs (Version 32) that we finalized in the FY 2015 IPPS/LTCH PPS final rule. In November 2014, we posted a Definitions Manual of the ICD–10 MS–DRGs Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.* The HAC code list translations from ICD–9–CM to ICD–10–CM/PCS are located in Appendix I of the ICD–10–CM/PCS MS–DRG Version 32 Definitions Manual. The link to this Manual (available in both text and HTML formats) is located in the Downloads section of the ICD–10 MS–DRG Conversion Project Web site.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24348 through 24349), we solicited public comments on how well the ICD–10–CM/PCS Version 32 HAC list replicates the ICD–9–CM Version 32 HAC list. We did not receive any public comments on our list of ICD–10 translations for the HAC list. Therefore, we are finalizing our proposal to implement the ICD–10–CM/PCS Version 33 HAC list to replace the ICD–9–CM Version 32 HAC list.

With respect to the current categories of the HACs, in the FY 2016 IPPS/LTCH PPS proposed rule, we did not propose to add or remove any categories for FY 2016.

Comment: Two commenters suggested that CMS expand the current HAC category of Iatrogenic Pneumothorax with Venous Catheterization to include Iatrogenic Pneumothorax with Thoracentesis and to also add Accidental Puncture/Bleeding with Paracentesis as a HAC category. The commenters cited various studies and asserted that both of these conditions satisfy the established criteria of being high cost, high volume, or both; being assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and could reasonably have been prevented through the application of evidence-based guidelines. Both commenters also listed a series of ICD–10–CM and ICD–10–PCS

codes that they requested CMS to consider for inclusion in each of these recommended new HAC categories. The commenters believed that adding these two conditions would improve patient care and result in cost savings to the Medicare program.

Response: We recognize and appreciate the commenters' recommendations for refinements to the HAC list. We also thank the commenters for their commitment to working with CMS on reducing complications resulting in better patient care and cost savings. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49879), we responded to similar comments and noted that we would take them under consideration for future rulemaking. While we did not propose to expand or add these specific HAC categories (Iatrogenic Pneumothorax with Thoracentesis and Accidental Puncture/Bleeding with Paracentesis) for FY 2016, in response to a public comment received last year, we did engage our contractor, RTI, to begin researching available evidence-based guidelines for these conditions. As discussed in section II.F.7. of the preamble to this final rule, RTI has completed their annual evidence-based guidelines report and, in addition, has developed a separate excerpt report that summarizes the two conditions recommended by the commenters under consideration. We encourage readers to review the separate document titled, ''Evidence-based Guidelines Pertaining to Select Thoracentesis- and Paracentesis-Related Conditions,'' which is available via the Internet on the CMS Hospital-Acquired Conditions Web page in the ''Downloads'' section at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond/* We reiterate that we continue to encourage public dialogue about refinements to the HAC list through written stakeholder comments.

We were unable to fully evaluate each of these two recommended conditions against all the established criteria, as well as review the references the commenters submitted, or perform detailed analysis of the ICD–10 codes that the commenters listed in time for discussion in this FY 2016 IPPS/LTCH PPS final rule. However, we intend to consider these public comments as we develop proposed changes to the HAC–POA program for FY 2017.

Comment: One commenter urged CMS to remove the Falls and Trauma HAC category from the HAC–POA program. The commenter stated that the statutory criterion that a condition could reasonably have been prevented through the application of evidence-based guidelines is not met for preventing falls. The commenter also stated that this HAC may lead to unintended consequences such as ''creating an epidemic of immobility in hospitals'' and excessive orders for bed rest and motion detection devices. The commenter recommended that CMS develop quality measures and incentivize hospitals to create Acute Care for Elders (ACE) units that focus on this specific population as another option. According to the commenter, studies of the ACE initiative determined better outcomes. For example, the commenter noted results of the ACE program model indicated a reduction in falls, delirium, and functional decline for patients, as well as shorter lengths of stay in a hospital, a decrease in the number of discharges to a nursing home, a reduction in 30-day readmissions, and reduced health care costs.

Response: We acknowledge the commenter's comments regarding the Falls and Trauma HAC category. With respect to the commenter's statement that one of the statutory criteria (that is, could reasonably have been prevented through the application of evidence-based guidelines) is not being met for the prevention of falls, we note that, as mentioned in response to an earlier comment, our contractor, RTI, has completed the 2015 Report for Evidence-Based Guidelines, which is available via the Internet on the CMS Hospital-Acquired Conditions Web page in the ''Downloads'' section at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond/*. We further note that evidence-based guidelines for falls prevention exist and refer the reader to the findings in this report directly related to falls. We also point out that, while the commenter requested the removal of the entire Falls and Trauma HAC category, falls are only one component (or condition) in the HAC category. The Falls and Trauma HAC category also includes conditions related to trauma, such as intracranial injuries, crushing injuries, burns, and other injuries (for example, frostbite, heat stroke, drowning, and suffocation). Therefore, we do not agree with the commenter's suggestion to remove the Falls and Trauma HAC category from the HAC–POA program.

In response to the commenter's recommendation that CMS establish quality measures and incentive payments for hospitals, we point out that currently, under various CMS quality reporting programs, there are measures specifically related to falls. On October 6, 2014, the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113–185) was enacted, which specified under section 1899B(c)(1) of the Act that the Secretary shall require postacute care providers to report data on quality measures relating to functional status, skin integrity, medication reconciliation and incidence of major falls. Prior to the IMPACT Act, the NQF #0674 measure, Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay), was finalized in the LTCHQR Program and the IRF QR Program. As such, we believe these measures specified in the IMPACT Act align with the CMS Quality Strategy,[4] which incorporates the three broad aims of the National Quality Strategy [5]:

- Better Care: Improve the overall quality of care by making healthcare more patient-centered, reliable, accessible and safe;
- Healthy People, Healthy Communities: Improve the health of the U.S. population by supporting proven interventions to address behavioral, social and environmental determinants of health in addition to delivering higher-quality care; and
- Affordable Care: Reduce the cost of quality healthcare for individuals, families, employers, and government.

Comment: One commenter requested that CMS incorporate untreated malnutrition, including disease-related malnutrition, as a HAC category. The commenter indicated there are three common types of malnutrition diagnoses that can be attributed to adults in healthcare settings: (1) Starvation-relation malnutrition; (2) chronic disease-related malnutrition; and (3) acute disease or injury-related malnutrition. The commenter also noted that hospital-acquired malnutrition from inadequate feeding practices is widespread. According to the commenter, screening patients for the detection of malnutrition allows for further follow-up sessions if warranted. In addition, the commenter stated that, through the process of early detection, the prevention and treatment for disease-related malnutrition will lead to improved outcomes such as patients acquiring fewer complications, hospitalizations, and readmissions.

The commenter suggested that CMS also advocate for the creation of quality measures that encourage nutrition screening, assessment, and intervention to be included in various quality

[4] Available at: *http://www.coms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[5] Available at: *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.html.*

reporting programs or other agency initiatives that focus on measuring quality of care.

Response: We appreciate the commenter's suggestion. As stated previously, we did not propose to add or remove any HAC categories for FY 2016. Therefore, we will consider this topic for future rulemaking. We encourage the commenter to submit the specific list of conditions, including the ICD–10 coded data identifying the various types of malnutrition that the commenter is recommending as a candidate condition, along with any additional supporting documentation, for the other established criteria for a HAC as referenced earlier in this section.

With regard to the commenter's recommendation to develop quality measures related to malnutrition in other quality reporting programs, we note that the quality reporting programs that involve measures are separate and distinct from the Deficit Reduction Act (DRA) HAC program. We refer the reader to section VII. of this FY 2016 IPPS/LTCH PPS final rule for information related to those programs.

We also refer readers to section II.F.6. of the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218) and to section II.F.7. of the FY 2009 IPPS final rule (73 FR 48774 through 48491) for detailed discussion supporting our determination regarding each of the current conditions. We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898) and final rule (77 FR 53285 through 53292) for the HAC policy for FY 2013, the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27509 through 27512) and final rule (78 FR 50523 through 50527) for the HAC policy for FY 2014, and the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28000 through 28003) and final rule (79 FR 49876 through 49880) for the HAC policy for FY 2015.

After consideration of the public comments we received, as we proposed, we are not adding or removing any HAC categories for FY 2016. However, as described more fully in section III.F.7. of the preamble of this final rule, we will continue to monitor contemporary evidence-based guidelines for selected, candidate, and previously considered HACs that provide specific recommendations for the prevention of the corresponding conditions in the acute hospital setting and may use this information to inform future rulemaking. In addition, we continue to encourage public dialogue about refinements to the HAC list through written stakeholder comments.

6. RTI Program Evaluation

On September 30, 2009, a contract was awarded to RTI to evaluate the impact of the Hospital-Acquired Condition-Present on Admission (HAC–POA) provisions on the changes in the incidence of selected conditions, effects on Medicare payments, impacts on coding accuracy, unintended consequences, and infection and event rates. This was an intra-agency project with funding and technical support from CMS, OPHS, AHRQ, and CDC. The evaluation also examined the implementation of the program and evaluated additional conditions for future selection. The contract with RTI ended on November 30, 2012. Summary reports of RTI's analysis of the FYs 2009, 2010, and 2011 Med PAR data files for the HAC–POA program evaluation were included in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50085 through 50101), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51512 through 51522), and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53292 through 53302). Summary and detailed data also were made publicly available on the CMS Web site at: *http://www.cms.gov/HospitalAcqCond/01_Overview.asp* and the RTI Web site at: *http://www.rti.org/reports/cms/*.

In addition to the evaluation of HAC and POA Med PAR claims data, RTI also conducted analyses on readmissions due to HACs, the incremental costs of HACs to the health care system, a study of spillover effects and unintended consequences, as well as an updated analysis of the evidence-based guidelines for selected and previously considered HACs. Reports on these analyses have been made publicly available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html*.

7. RTI Reports on Evidence-Based Guidelines

The RTI program evaluation included a report that provided references for all evidence-based guidelines available for each of the selected, candidate, and previously considered HACs that provided specific recommendations for the prevention of the corresponding conditions. Guidelines were primarily identified using the AHRQ National Guidelines Clearing House (NGCH) and the CDC, along with relevant professional societies. Guidelines published in the United States were used, if available. In the absence of U.S. guidelines for a specific condition, international guidelines were included.

RTI prepared a final report to summarize its findings regarding these guidelines. This report is titled ''Evidence-Based Guidelines for Selected, Candidate, and Previously Considered Hospital-Acquired Conditions'' and can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Downloads/Evidence-Based-Guidelines.pdf*.

Subsequent to this final report, RTI was awarded a new Evidence-Based Guidelines Monitoring contract. Under this monitoring contract, RTI annually provides a summary report of the contemporary evidence-based guidelines for selected, candidate, and previously considered HACs that provide specific recommendations for the prevention of the corresponding conditions in the acute care hospital setting. We received RTI's 2015 report and are making it available to the public on the CMS Hospital-Acquired Conditions Web page in the ''Downloads'' section at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond/*.

G. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

Providers use the code sets under the ICD–9–CM coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system. A later coding edition, 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 Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting. The ICD–10 coding system was initially adopted for transactions conducted on or after October 1, 2013, as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS Final Rule published in the **Federal Register** on January 16, 2009 (74 FR 3328 through 3362) (hereinafter referred to as the ''ICD–10–CM and ICD–10–PCS final rule''). However, the Secretary of

Health and Human Services issued a final rule that delayed the compliance date for ICD–10 from October 1, 2013, to October 1, 2014. That final rule, entitled ''Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD–10–CM and ICD–10–PCS Medical Data Code Sets,'' CMS–0040–F, was published in the **Federal Register** on September 5, 2012 (77 FR 54664) and is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf*. On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included a new compliance date that requires the use of ICD–10 beginning October 1, 2015. The August 4, 2014 final rule is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2014-08-04/pdf/2014-18347.pdf*. That final rule also requires HIPAA covered entities to continue to use ICD–9–CM through September 30, 2015.

The anticipated move to ICD–10 necessitated the development of an ICD–10–CM/ICD–10–PCS version of the MS–DRGs. CMS began a project to convert the ICD–9–CM-based MS–DRGs to ICD–10 MS–DRGs. In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received public comments on the creation of the ICD–10 version of the MS–DRGs, which will be implemented at the same time as ICD–10 (75 FR 50127 and 50128). While we did not propose an ICD–10 version of the MS–DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting current MS–DRGs from ICD–9–CM codes to ICD–10 codes and sharing this information through the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to implement their own conversion projects. We posted ICD–10 MS–DRGs based on Version 26.0 (FY 2009) of the MS–DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for other payers and providers to follow. Information on the ICD–10 MS–DRG conversion project can be found on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We have continued to keep the public updated on our maintenance efforts for ICD–10–CM and ICD–10–PCS coding systems, as well as the General Equivalence Mappings that assist in conversion through the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee. Information on these committee meetings can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

During FY 2011, we developed and posted Version 28 of the ICD–10 MS–DRGs based on the FY 2011 MS–DRGs (Version 28) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD–10 MS–DRGs Version 28 also included the CC Exclusion List and the ICD–10 version of the hospital-acquired conditions (HACs), which was not posted with Version 26. We also discussed this update at the September 15–16, 2010 and the March 9–10, 2011 meetings of the ICD–9–CM Coordination and Maintenance Committee. The minutes of these two meetings are posted on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

We reviewed public comments on the ICD–10 MS–DRGs Version 28 and made updates as a result of these comments. We called the updated version the ICD–10 MS–DRGs Version 28–R1. We posted a Definitions Manual of ICD–10 MS–DRGs Version 28–R1 on our ICD–10 MS–DRG Conversion Project Web site. To make the review of Version 28–R1 updates easier for the public, we also made available pilot software on a CD ROM that could be ordered through the National Technical Information Service (NTIS). A link to the NTIS ordering page was provided on the CMS ICD–10 MS–DRGs Web page. We stated that we believed that, by providing the ICD–10 MS–DRGs Version 28–R1 Pilot Software (distributed on CD ROM), the public would be able to more easily review and provide feedback on updates to the ICD–10 MS–DRGs. We discussed the updated ICD–10 MS–DRGs Version 28–R1 at the September 14, 2011 ICD–9–CM Coordination and Maintenance Committee meeting. We encouraged the public to continue to review and provide comments on the ICD–10 MS–DRGs so that CMS could continue to update the system.

In FY 2012, we prepared the ICD–10 MS–DRGs Version 29, based on the FY 2012 MS–DRGs (Version 29) that we finalized in the FY 2012 IPPS/LTCH PPS final rule. We posted a Definitions Manual of ICD–10 MS–DRGs Version 29 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 28 to Version 29 to facilitate a review. The ICD–10 MS–DRGs Version 29 was discussed at the ICD–9–CM Coordination and Maintenance Committee meeting on March 5, 2012. Information was provided on the types of updates made. Once again, the public was encouraged to review and comment on the most recent update to the ICD–10 MS–DRGs.

CMS prepared the ICD–10 MS–DRGs Version 30 based on the FY 2013 MS–DRGs (Version 30) that we finalized in the FY 2013 IPPS/LTCH PPS final rule. We posted a Definitions Manual of the ICD–10 MS–DRGs Version 30 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 29 to Version 30 to facilitate a review. We produced mainframe and computer software for Version 30, which was made available to the public in February 2013. Information on ordering the mainframe and computer software through NTIS was posted on the ICD–10 MS–DRG Conversion Project Web site. The ICD–10 MS–DRGs Version 30 computer software facilitated additional review of the ICD–10 MS–DRGs conversion.

We provided information on a study conducted on the impact of converting MS–DRGs to ICD–10. Information on this study is summarized in a paper entitled ''Impact of the Transition to ICD–10 on Medicare Inpatient Hospital Payments.'' This paper was posted on the CMS ICD–10 MS–DRGs Conversion Project Web site and was distributed and discussed at the September 15, 2010 ICD–9–CM Coordination and Maintenance Committee meeting. The paper described CMS' approach to the conversion of the MS–DRGs from ICD–9–CM codes to ICD–10 codes. The study was undertaken using the ICD–9–CM MS–DRGs Version 27 (FY 2010), which was converted to the ICD–10 MS–DRGs Version 27. The study estimated the impact on aggregate payment to hospitals and the distribution of payments across hospitals. The impact of the conversion from ICD–9–CM to ICD–10 on Medicare MS–DRG hospital payments was estimated using FY 2009 Medicare claims data. The study found a hospital payment increase of 0.05 percent using the ICD–10 MS–DRGs Version 27.

CMS provided an overview of this hospital payment impact study at the March 5, 2012 ICD–9–CM Coordination and Maintenance Committee meeting.

This presentation followed presentations on the creation of ICD–10 MS–DRGs Version 29. A summary report of this meeting can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*. At the March 2012 meeting, CMS announced that it would produce an update on this impact study based on an updated version of the ICD–10 MS–DRGs. This update of the impact study was presented at the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting. The study found that moving from an ICD–9–CM-based system to an ICD–10 MS–DRG replicated system would lead to DRG reassignments on only 1 percent of the 10 million MedPAR sample records used in the study. Ninety-nine percent of the records did not shift to another MS–DRG when using an ICD–10 MS–DRG system. For the 1 percent of the records that shifted, 45 percent of the shifts were to a higher weighted MS–DRG, while 55 percent of the shifts were to lower weighted MS–DRGs. The net impact across all MS–DRGs was a reduction by 4/10000 or minus 4 pennies per $100. The updated paper is posted on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Downloads'' section. Information on the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*. This update of the impact paper and the ICD–10 MS–DRG Version 30 software provided additional information to the public who were evaluating the conversion of the MS–DRGs to ICD–10 MS–DRGs.

CMS prepared the ICD–10 MS–DRGs Version 31.0 based on the FY 2014 MS–DRGs (Version 31) that we finalized in the FY 2014 IPPS/LTCH PPS final rule. In November 2013, we posted a Definitions Manual of the ICD–10 MS–DRGs Version 31 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that described changes made from Version 30 to Version 31 to facilitate a review. We produced mainframe and computer software for Version 31, which was made available to the public in December 2013. Information on ordering the mainframe and computer software through NTIS was posted on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. This ICD–10 MS–DRGs Version 31 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect grouping logic found in the ICD–9–CM MS–DRGs Version 31.

We reviewed public comments received and developed an update of ICD–10 MS–DRGs Version 31, which we called ICD–10 MS–DRGs Version 31.0–R. We made available a Definitions Manual of the ICD–10 MS–DRGs Version 31.0–R on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that describes changes made from Version 31 to Version 31–R to facilitate a review. We will continue to share ICD–10–MS–DRG conversion activities with the public through this Web site.

CMS prepared the ICD–10 MS–DRGs Version 32 based on the FY 2015 MS–DRGs (Version 32) that we finalized in the FY 2015 IPPS/LTCH PPS final rule. In November 2014, we made available a Definitions Manual of the ICD–10 MS DRGs Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that described changes made from Version 31–R to Version 32 to facilitate a review. We produced mainframe and computer software for Version 32, which was made available to the public in January 2015. Information on ordering the mainframe and computer software through NTIS was made available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. This ICD–10 MS–DRGs Version 32 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect grouping logic found in the ICD–9–CM MS–DRGs Version 32. We discuss five requests from the public to update the ICD–10 MS–DRGs Version 32 to better replicate the ICD–9–CM MS–DRGs in section II.G.3., 4., and 5. of the preamble of this FY 2016 IPPS/LTCH PPS final rule. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24351), we proposed to implement the MS–DRG code logic in the ICD–10 MS–DRGs Version 32 along with any finalized updates to the ICD–10 MS–DRGs Version 32 for the final ICD–10 MS–DRGs Version 33. In the proposed rule, we proposed the ICD–10 MS–DRGs Version 33 as the replacement logic for the ICD–9–CM based MS–DRGs Version 32 as part of the proposed MS–DRG updates for FY 2016. We invited public comments on how well the ICD–10 MS–DRGs Version 32 replicates the logic of the MS–DRGs Version 32 based on ICD–9–CM codes.

Comment: One commenter addressed an ICD–10 MS–DRG replication issue regarding the procedure code designation and MS–DRG assignment of two ICD–10–PCS codes in the ICD–10 MS–DRGs Version 32 Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code MS–DRG Index. The commenter agreed with CMS that the two ICD–10–PCS codes identified in the FY 2016 IPPS/LTCH PPS proposed rule, 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach) and 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach), were appropriate translations for ICD–9–CM procedure code 38.26 (Insertion of implantable wireless pressure sensor without lead for intracardiac or great vessel hemodynamic monitoring), which identifies the CardioMEMS™ HF Monitoring System (80 FR 24426). However, the commenter noted that, under the ICD–9–CM based MS–DRGs Version 32 logic, procedure code 38.26 is designated as an operating room (O.R.) procedure for MS–DRG assignment and group to MS–DRG 264 (Other Circulatory O.R. Procedures), while under the ICD–10 based MS–DRGs Version 32 logic, the two ICD–10–PCS code translations are not recognized as O.R. procedures for purposes of MS–DRG assignment. Therefore, the commenter requested that the two ICD–10–PCS codes be designated as O.R. procedures within Appendix E of the ICD–10 MS–DRG Definitions Manual and group to ICD–10 MS–DRG 264 to accurately replicate the ICD–9–CM MS–DRG Version 32 logic.

Response: We agree with the commenter that this is an ICD–10 MS–DRG replication error. ICD–10–PCS codes 02HQ30Z and 02HR30Z, along with the other ICD–10–PCS codes describing the insertion of a pressure sensor monitoring device that are also appropriate translations for ICD–9–CM procedure code 38.26, should be designated as O.R. procedures within Appendix E of the ICD–10 MS–DRG

Definitions Manual and assigned to ICD–10 MS–DRG 264 to accurately replicate the ICD–9–CM MS–DRGs Version 32 logic. These other ICD–10–PCS codes describe the insertion of a pressure sensor monitoring device utilizing an open approach or a percutaneous endoscopic approach (for the right or left pulmonary artery). Therefore, to be consistent with the comparable ICD–10–PCS code translations describing a percutaneous approach and to accurately replicate the ICD–9–CM MS–DRGs Version 32 logic for ICD–9–CM procedure code 38.26, the ICD–10–PCS codes listed below that describe the insertion of a pressure sensor monitoring device utilizing an open approach or a percutaneous endoscopic approach (for the right or left pulmonary artery) should also be designated as O.R. procedures and assigned to ICD–10 MS–DRG 264.

After consideration of the public comments we received, as final policy for the FY 2016 ICD–10 MS–DRGs Version 33, we are designating the following ICD–10–PCS codes as O.R. procedures and assigning them to ICD–10 MS–DRG 264:

- 02HQ00Z (Insertion of pressure sensor monitoring device into right pulmonary artery, open approach);
- 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach);
- 02HQ40Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous endoscopic approach);
- 02HR00Z (Insertion of pressure sensor monitoring device into left pulmonary artery, open approach);
- 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach); and
- 02HR40Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous endoscopic approach).

Comment: One commenter addressed an ICD–10 MS–DRG replication issue concerning excisional debridements of deep pressure ulcers of the ankle. The commenter recommended that the following two ICD–10–PCS codes be added to ICD–10 MS–DRG 581 (Other Skin, Subcutaneous Tissue and Breast Procedures without CC/MCC) to accurately replicate the ICD–9–CM MS–DRG logic: ICD–10–PCS procedure code 0LBT0ZZ (Excision of left ankle tendon, open approach) and ICD–10–PCS procedure code 0LBS0ZZ (Excision of right ankle tendon, open approach). The commenter stated that the ICD–9–CM procedure codes describing the excisional debridements of pressure ulcers that extend down into the ankle tendon are currently assigned to MS–DRG 581. However, the ICD–10–PCS codes capturing these procedures are not in the ICD–10–PCS MS–DRG 581.

Response: We agree with the commenter that this is an ICD–10 MS–DRG replication error. ICD–9–CM code 83.39 (Excision of lesion of other soft tissue) captures this procedure and is assigned to ICD–9 MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively). Therefore, ICD–10–PCS codes 0LBT0ZZ and 0LBS0ZZ also should be assigned to ICD–10 MS–DRGs 579, 580, and 581.

After consideration of the public comments received, we are assigning ICD–10–PCS procedure codes 0LBT0ZZ (Excision of left ankle tendon, open approach) and 0LBS0ZZ (Excision of right ankle tendon, open approach) to ICD–10 MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively).

Comment: One commenter addressing an ICD–10 MS–DRG replication issue requested that CMS add the following four post-delivery procedure codes to the ICD–10 version of MS–DRGs 774 and 775 (Vaginal Delivery with and without Complicating Diagnoses, respectively) under the ''Only Operating Room Procedures'' section. The commenter stated that these codes are currently assigned to the ICD–9–CM version of MS–DRGs 774 and 775.

- 0HBJXZZ (Excision of left upper leg skin, external approach);
- 0DQR0ZZ (Repair anal sphincter, open approach (3rd degree obstetrical laceration repair);
- OUQJXZZ (Repair clitoris, external approach); and
- 0UBMXZZ (Excision of vulva, external approach).

The following table shows the equivalent ICD–9–CM codes provided by the requestor.

ICD–10–PCS Procedure code	ICD–9–CM Procedure code
0UBMXZZ (Excision of vulva, external approach)	71.3 (Other local excision or destruction of vulva and perineum).
0DQR0ZZ (Repair anal sphincter, open approach (3rd degree obstetrical laceration repair).	75.61(Repair of current obstetric laceration of rectum and sphincter ani).
0UQJXZZ (Repair clitoris, external approach)	75.69 (Repair of current obstetric laceration).
0HBJXZZ (Excision of left upper leg skin, external approach)	86.3 (Local excision/destruction of lesion/tissue of skin and subcutaneous tissues).

Response: We examined the list of post-delivery procedure codes in ICD–9 MS–DRGs 774 and 775 under the ''Only Operating Room Procedures'' section and found that ICD–9–CM procedure code 71.3 is included. Therefore, we agree with the commenter that this oversight is a replication error and that ICD–10–PCS procedure code 0UBMXZZ should be assigned to ICD–10 MS–DRGs 774 and 775 under the ''Only Operating Room Procedures'' section. However, with regard to ICD–9–CM procedure codes 75.61, 75.69, and 86.3, when we examined the list of post-delivery procedure codes in MS–DRGs 774 and 775 under the ''Only Operating Room Procedures'' section, we found that they were not included. Therefore, we disagree with adding ICD–10–PCS codes 0DQR0ZZ, 0UQJXZZ, and 0HBJXZZ to ICD–10 MS–DRGs 774 and 775 under the ''Only operating room Procedures'' section because these procedures are not currently captured in ICD–9 MS–DRGs 774 and 775. The omission of these three ICD–10–PCS codes is not an ICD–10 MS–DRG replication error.

After consideration of the public comments received, we are assigning ICD–10–PCS code 0UBMXZZ (Excision of vulva, external approach) to ICD–10 MS–DRGs 774 and 775 (Vaginal Delivery with and without Complicating Diagnoses, respectively) under the ''Only Operating Room Procedures'' section.

b. Basis for FY 2016 MS–DRG Updates

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December 7 of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2016, comments and suggestions should have been submitted by December 7, 2014. The comments that were submitted in a timely manner for

FY 2016 are discussed below in this section.

Following are the changes we proposed to the MS–DRGs and our finalized policies for FY 2016. We invited public comments on each of the MS–DRG classification proposed changes described below, as well as our proposals to maintain certain existing MS–DRG classifications, which also are discussed below. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we proposed to maintain the existing MS–DRG classification based on our analysis of claims data. For the FY 2016 proposed rule, our MS–DRG analysis was based on claims data from the December 2014 update of the FY 2014 MedPAR file, which contains hospital bills received through September 30, 2014, for discharges occurring through September 30, 2014. In our discussion of the MS–DRG reclassification changes that follows, we refer to our analysis of claims data from the ''December 2014 update of the FY 2014 MedPAR file.''

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose and to make further modification 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 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 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. Furthermore, 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.
- 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. MDC 1 (Diseases and Disorders of the Nervous System): Endovascular Embolization (Coiling) Procedures

We received a request again this year to change the MS–DRG assignment for endovascular embolization (coiling) procedures. This topic was discussed previously in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28005 through 28006) and in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49883 through 49886). For FY 2015, we did not change the MS–DRG assignment for endovascular embolization (coiling) procedures.

After issuance of the FY 2015 IPPS/LTCH PPS final rule, we received a modified request from the commenter asking that CMS consider establishing four new MS–DRGs:

- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures with Principal Diagnosis of Hemorrhage);
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with MCC);
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with CC); and
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage without CC/MCC).

The requestor stated that establishing these new suggested MS–DRGs will promote clinical cohesiveness and resource comparability. The requestor stated that endovascular intracranial and endovascular embolization procedures are not similar to the open craniotomy procedures with which they are currently grouped. The requestor asserted that the differences in costs between endovascular intracranial procedures and open craniotomy procedures are significant, reflecting, for instance, the use of an operating suite versus an interventional vascular catheterization laboratory suite, intensive care and other costs.

In conjunction with the recommended new MS–DRGs, the requestor recommended that the following ICD–9–CM codes, which include endovascular embolization procedures and additional intracranial procedures, be removed from MS–DRG 020 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with MCC); MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC); MS–DRG 022 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage without CC/MCC); MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant); MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC); MS–DRG 025 (Craniotomy & Endovascular Intracranial Procedures with MCC); MS–DRG 026 (Craniotomy & Endovascular Intracranial Procedures with CC); and MS–DRG 027 (Craniotomy & Endovascular Intracranial Procedures without CC/MCC):

- 00.62 (Percutaneous angioplasty of intracranial vessel);
- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.74 (Endovascular removal of obstruction from head and neck vessel(s));
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils);
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils); and
- 39.79 (Other endovascular procedures on other vessels).

The requestor asked that the four new requested MS–DRGs be created using these procedure codes. The requestor suggested that the first requested new MS–DRG would be MS–DRG XXX (Endovascular Intracranial Embolization Procedures with Principal Diagnosis of Hemorrhage). The principal diagnoses for hemorrhage would include the same hemorrhage codes in the current MS–DRGs 020, 021, and 022, which are as follows:

- 094.87 (Syphilitic ruptured cerebral aneurysm);
- 430 (Subarachnoid hemorrhage);
- 431 (Intracerebral hemorrhage);
- 432.0 (Nontraumatic extradural hemorrhage);
- 432.1 (Subdural hemorrhage); and
- 432.9 (Unspecified intracranial hemorrhage).

For this first new requested MS–DRG, the requestor suggested that only the

following endovascular embolization procedure codes would be assigned:

- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils); and
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils).

The requestor recommended that the three additional new MS–DRGs would consist of a new base MS–DRG subdivided into three severity levels as follows:

- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with MCC);
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with CC); and
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage without CC/MCC).

The requestor suggested that these three new recommended MS–DRGs would have endovascular embolization procedures as well as additional percutaneous and endovascular procedures as listed below:

- 00.62 (Percutaneous angioplasty of intracranial vessel);
- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.74 (Endovascular removal of obstruction from head and neck vessel(s));
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils);
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils); and
- 39.79 (Other endovascular procedures on other vessels).

ICD–10–PCS provides the following more detailed codes for endovascular embolization, which are assigned to MS–DRGs 020, 021, 022, 023, 024, 025, 026, and 027 in the ICD–10 MS–DRGs Version 32:

ICD–10–PCS Codes for Endovascular Embolization Assigned to MS–DRGs 020 Through 027 in ICD–10 MS–DRGs Version 32

ICD–10–PCS Code	Code description
03LG3BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous approach.
03LG3DZ	Occlusion of intracranial artery with intraluminal device, percutaneous approach.
03LG4BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LG4DZ	Occlusion of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03LH3BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03LH3DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous approach.
03LH4BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LH4DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LJ3BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03LJ3DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous approach.
03LJ4BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LJ4DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LK3BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LK3DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous approach.
03LK4BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LK4DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LL3BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LL3DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous approach.
03LL4BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LL4DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LM3BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03LM3DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous approach.
03LM4BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LM4DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LN3BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03LN3DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous approach.
03LN4BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LN4DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LP3BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03LP3DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous approach.
03LP4BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LP4DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LQ3BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03LQ3DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous approach.
03LQ4BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LQ4DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LR3DZ	Occlusion of face artery with intraluminal device, percutaneous approach.
03LR4DZ	Occlusion of face artery with intraluminal device, percutaneous endoscopic approach.
03LS3DZ	Occlusion of right temporal artery with intraluminal device, percutaneous approach.
03LS4DZ	Occlusion of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03LT3DZ	Occlusion of left temporal artery with intraluminal device, percutaneous approach.
03LT4DZ	Occlusion of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VG3BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous approach.
03VG3DZ	Restriction of intracranial artery with intraluminal device, percutaneous approach.
03VG4BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VG4DZ	Restriction of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03VH3BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous approach.

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION ASSIGNED TO MS–DRGS 020 THROUGH 027 IN ICD–10 MS–DRGS VERSION 32—Continued

ICD–10–PCS Code	Code description
03VH3DZ	Restriction of right common carotid artery with intraluminal device, percutaneous approach.
03VH4BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VH4DZ	Restriction of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VJ3BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03VJ3DZ	Restriction of left common carotid artery with intraluminal device, percutaneous approach.
03VJ4BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VJ4DZ	Restriction of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VK3BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VK3DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous approach.
03VK4BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VK4DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VL3BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VL3DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous approach.
03VL4BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VL4DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VM3BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03VM3DZ	Restriction of right external carotid artery with intraluminal device, percutaneous approach.
03VM4BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VM4DZ	Restriction of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VN3BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03VN3DZ	Restriction of left external carotid artery with intraluminal device, percutaneous approach.
03VN4BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VN4DZ	Restriction of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VP3BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03VP3DZ	Restriction of right vertebral artery with intraluminal device, percutaneous approach.
03VP4BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VP4DZ	Restriction of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VQ3BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03VQ3DZ	Restriction of left vertebral artery with intraluminal device, percutaneous approach.
03VQ4BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VQ4DZ	Restriction of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VR3DZ	Restriction of face artery with intraluminal device, percutaneous approach.
03VR4DZ	Restriction of face artery with intraluminal device, percutaneous endoscopic approach.
03VS3DZ	Restriction of right temporal artery with intraluminal device, percutaneous approach.
03VS4DZ	Restriction of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03VT3DZ	Restriction of left temporal artery with intraluminal device, percutaneous approach.
03VT4DZ	Restriction of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VU3DZ	Restriction of right thyroid artery with intraluminal device, percutaneous approach.
03VU4DZ	Restriction of right thyroid artery with intraluminal device, percutaneous endoscopic approach.
03VV3DZ	Restriction of left thyroid artery with intraluminal device, percutaneous approach.
03VV4DZ	Restriction of left thyroid artery with intraluminal device, percutaneous endoscopic approach.

For this request, as discussed in the FY 2016 IPPS/LTCH PPS proposed rule, we first examined claims data for all intracranial vascular procedure cases with a principal diagnosis of hemorrhage reported in MS–DRGs 020, 021, and 022 in the December 2014 update of the FY 2014 MedPAR file. The table below shows our findings. We found a total of 1,755 cases with an average length of stay ranging from 8.28 days to 16.84 days and average costs ranging from $36,998 to $71,665 in MS–DRGs 020, 021, and 022.

INTRACRANIAL VASCULAR PROCEDURES WITH PRINCIPAL DIAGNOSIS OF HEMORRHAGE

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 020 (with MCC)—All cases	1,285	16.84	$71,655
MS–DRG 021 (with CC)—All cases	372	13.82	52,143
MS–DRG 022 (without CC/MCC)—All cases	98	8.28	36,998

Next, we examined claims data on the first part of the request, which was to create a new MS–DRG for endovascular intracranial embolization procedure cases with a principal diagnosis of hemorrhage that are currently assigned to MS–DRGs 020, 021, and 022. Our findings for the first part of this multi-part request are shown in the table below.

ENDOVASCULAR INTRACRANIAL EMBOLIZATION PROCEDURES WITH PRINCIPAL DIAGNOSIS OF HEMORRHAGE

MS–DRG	Number of cases	Average length of stay	Average costs
Requested new combined MS–DRG	1,275	15.6	$67,831

The requestor suggested that this new requested base MS–DRG would not be subdivided by severity levels. Using the requested code logic, cases with a principal diagnosis of hemorrhage and procedure codes 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels), 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils), and 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils) would be moved out of MS–DRGs 020, 021, and 022 and into a single new MS–DRG with no severity levels.

As can be seen in the table above, the average costs for the new requested combined MS–DRG would be $67,831. The average costs for current MS–DRGs 020, 021, and 022 were $71,655, $52,143, and $36,998, respectively. Based on these findings, if we established this requested new MS–DRG, payments for those cases at the highest severity level (MS–DRG 020, which had average costs of $71,655) would be reduced.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24351 through 24356), we stated that we believe that maintaining the current MS–DRG assignment for these types of procedures is appropriate. Our clinical advisors stated that the current grouping of procedures within MS–DRGs 020, 021, and 022 reflects patients who are unique in terms of utilization and complexity based on the three severity levels, which are specifically designed to capture clinical differences in these patients, and these factors support maintaining the current structure. Therefore, we did not propose to move cases with a principal diagnosis of hemorrhage and procedure codes 39.72, 39.75, and 39.76 out of MS–DRGs 020, 021, and 022 and create a new base MS–DRG. We invited public comments on this proposal.

As discussed earlier in this section, the requestor also recommended the creation of a new set of MS–DRGs for endovascular intracranial embolization procedures without a principal diagnosis of hemorrhage with MCC, with CC, and without CC/MCC. For these requested new MS–DRGs, the requestor suggested assignment of endovascular embolization procedures as well as certain other percutaneous and endovascular procedures. The complete list of endovascular intracranial embolization procedures developed by the requestor is as follows:

- 00.62 (Percutaneous angioplasty of intracranial vessel);
- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.74 (Endovascular removal of obstruction from head and neck vessel(s));
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils);
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils); and
- 39.79 (Other endovascular procedures on other vessels)

The following table shows our findings from examination of claims data on endovascular intracranial procedures without a principal diagnosis of hemorrhage reported in MS–DRGs 023 through 027 from the December 2014 update of the FY 2014 MedPAR file.

ENDOVASCULAR INTRACRANIAL PROCEDURES WITHOUT PRINCIPAL DIAGNOSIS OF HEMORRHAGE

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 023—All cases	5,615	10.96	$37,784
MS–DRG 023—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	1,510	8.88	39,666
MS–DRG 024—All cases	1,848	5.93	26,195
MS–DRG 024—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	867	5.80	27,975
MS–DRG 025—All cases	16,949	9.35	29,970
MS–DRG 025—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	650	8.52	44,082
MS–DRG 026—All cases	8,075	6.09	21,414
MS–DRG 026—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	778	3.07	26,594
MS–DRG 027—All cases	9,883	3.15	16,613
MS–DRG 027—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	1,793	1.66	22,244

As can be seen from this table, if we created a new set of MS–DRGs recommended by the requester, most of the cases would have to be moved out of MS–DRGs 023 and 027. The 1,510 cases that would have to be moved out of MS–DRG 023 have average costs of $39,666 compared to average costs of $37,784 for all cases in MS–DRG 023. The average costs for these cases are not significantly different from the average costs for all cases in MS–DRG 023. The average length of stay for the cases with endovascular intracranial procedure without a diagnosis of hemorrhage in MS–DRG 023 is 8.88 compared to 10.96 days for all cases in MS–DRG 023. In the proposed rule, we stated that we believe that these data support the current MS–DRG assignment for MS–DRG 023. The 1,793 cases that would have to be moved out of MS–DRG 027 have average costs of $22,244 compared to the average costs of $16,613 for all cases in MS–DRG 027. While the average costs for these cases are higher than for all cases in MS–DRG 027, one would

expect some procedures within an MS–DRG to have higher average costs and other procedures to have lower average costs than the overall average costs. Cases within the MS–DRGs describing endovascular intracranial procedures are grouped together based on similar clinical and resource criteria. Some cases will have average costs that are higher than the overall average costs for cases in the MS–DRG, while other cases will have lower average costs. These differences in average costs are found within all MS–DRGs. The average length of stay of MS–DRG 027 cases with endovascular intracranial procedure without a diagnosis of hemorrhage is 1.66 days as compared to 3.15 days for all cases in MS–DRG 027. Therefore, while the average costs are higher for the cases with endovascular intracranial procedure without a diagnosis of hemorrhage than for all cases in MS–DRG 027, the length of stay is shorter.

The 867 cases that would have to be moved out of MS–DRG 024 have average costs of $27,975 compared to average costs for all cases in MS–DRG 024 of $26,195. The average costs for these cases are not significantly different than the average costs for all cases in MS–DRG 024. The average length of stay for the 867 cases that would have to be moved out of MS–DRG 024 is 5.80 compared to 5.93 for all cases in MS–DRG 024. Therefore, the lengths of stay for the cases also are quite similar in MS–DRG 024. In the FY 2016 IPPS/LTCH PPS proposed rule, we stated that we determined that these data findings support maintaining the current MS–DRG assignment of these procedures in MS–DRG 024.

MS–DRGs 025 and 026 show the smallest number of cases that would have to be moved to the requested new MS–DRGs, but these cases have larger differences in average costs. The average costs of cases that would have to be moved out of MS–DRG 025 are $44,082 compared to $29,970 for all cases in MS–DRG 025. The average length of stay for the MS–DRG 025 cases with endovascular intracranial procedure without a diagnosis of hemorrhage is 8.52 days as compared to 9.35 days for all cases in MS–DRG 025. Therefore, the lengths of stay are similar for cases in MS–DRG 025. The average costs of cases that would have to be moved out of MS–DRG 026 are $26,594 compared to $21,414 for all cases. The average length of stay for cases that would have to be moved out of MS–DRG 026 is 3.07 days compared to 6.09 days for all cases in MS–DRG 026, or almost half as long as for all cases in MS–DRG 026. As stated earlier, the average costs for cases that would be moved out of MS–DRGs 023, 024, 025, 026, and 027 under this request are higher than the average costs for all cases in these MS–DRGs, with most of the cases coming out of MS–DRGs 023 and 027. The average costs for these particular cases in MS–DRG 023 are not significantly different from the average costs for all cases in MS–DRG 023. In addition, while the average costs are higher for the cases with an endovascular intracranial procedure without a diagnosis of hemorrhage than for all cases in MS–DRG 027, the length of stay is shorter. We determined that the overall data do not support making the requested MS–DRG updates to MS–DRGs 023, 024, 025, 026, and 027 and creating three new MS–DRGs. Therefore, we did not propose to make changes to the current structure for MS–DRGs 023 through 027.

In summary, our clinical advisors reviewed each aspect of this multi-part request and advised us that the endovascular embolization procedures are appropriately assigned to MS–DRGs 020 through 027. They did not support removing the procedures (procedure codes 39.72, 39.75, and 39.76) from MS–DRGs 020, 021, and 022 and creating a single MS–DRG for endovascular intracranial embolization procedures with a principal diagnosis of hemorrhage with no severity levels. Our clinical advisors stated that the current MS–DRG grouping of three severity levels captures differences in clinical severity, average costs, and length of stay for these patients appropriately. Our clinical advisors also recommended maintaining the current MS–DRG assignments for endovascular embolization and other percutaneous and endovascular procedures within MS–DRGs 023 through 027. They stated that these procedures are all clinically similar to others in these MS–DRGs. In addition, they stated that the surgical techniques are all designed to correct the same clinical problem, and they advised against moving a select number of those procedures out of MS–DRGs 023 through 027.

Based on the findings from our data analysis and the recommendations from our clinical advisors, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24356), we did not propose to create the four new MS–DRGs for endovascular intracranial embolization and other endovascular procedures recommended by the requestor. We proposed to maintain the current MS–DRG structure for MS–DRGs 020 through 027.

We invited public comments on these two proposals.

Comment: A number of commenters supported the proposal to maintain the current MS–DRG structure for MS–DRGs 020 through 027 and not to create four new MS–DRGs for endovascular intracranial embolization and other endovascular procedures. The commenters stated that the proposal was reasonable, given the data and information provided.

One commenter disagreed with the proposal. The commenter stated that the data demonstrate that the cost of endovascular coil cases consistently exceeds the overall average cost of all cases within each of the MS–DRGs to which these procedures are currently assigned. Moreover, the commenter believed that it was inappropriate to minimize the clinical complexity of these procedures compared to other procedures in the current MS–DRGs.

Response: We appreciate the commenters' support for our proposal to maintain the current MS–DRG structure for MS–DRGs 020 through 027 and not to create four new MS–DRGs for endovascular intracranial embolization and other endovascular procedures. In response to the commenter who disagreed with the proposal, as stated earlier in this section, while we recognize that the average costs of these cases are higher than the average costs of all cases in MS–DRGs 023 through 027, one would expect some procedures within an MS–DRG to have higher average costs and other procedures to have lower average costs than the overall average costs. Cases within the MS–DRGs describing endovascular intracranial procedures are grouped together based on similar clinical and resource criteria. Some cases will have average costs that are higher than the overall average costs for cases in the MS–DRG, while other cases will have lower average costs. Our clinical advisors recommended maintaining the current MS–DRG assignments for endovascular embolization and other percutaneous and endovascular procedures within MS–DRGs 023 through 027. They continue to believe that these procedures are all clinically similar to others in these MS–DRGs and that the surgical techniques are all designed to correct the same clinical problem, and continue to advise against moving a select number of those procedures out of MS–DRGs 020 through 027. Our clinical advisors stated that the endovascular intracranial embolizations and other endovascular procedures address the same clinical problems as other procedures assigned to MS–DRGs 020 through 027. Therefore, the cases in MS–DRGs 020 through 027 are clinically similar.

After consideration of the public comments we received, we are finalizing our proposal to maintain the

current MS–DRG structure for MS–DRGs 020 through 027 and not to create four new MS–DRGs for endovascular intracranial embolization and other endovascular procedures.

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Adding Severity Levels to MS–DRGs 245 Through 251

During the comment period for the FY 2015 IPPS/LTCH PPS proposed rule, we received a comment that recommended establishing severity levels for MS–DRG 245 (AICD Generator Procedures) and including additional severity levels for MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents); MS–DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC); MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents); MS–DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC); MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC); and MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC).

We considered this public comment to be outside of the scope of the FY 2015 IPPS/LTCH PPS proposed rule. Therefore, we did not address this comment in the FY 2015 IPPS/LTCH PPS final rule. However, we indicated that we would consider the public comment for possible proposals in future rulemaking as part of our annual review process.

For the FY 2016 IPPS/LTCH PPS proposed rule, we received a separate, but related, request involving most of these same MS–DRGs. Therefore, for the FY 2016 IPPS/LTCH PPS proposed rule, we conducted a simultaneous analysis of claims data to address both the FY 2015 public comment request and the related FY 2016 request. We discuss both of these requests below.

b. Percutaneous Intracardiac Procedures

We received a request to remove the cardiac ablation and other specified cardiovascular procedures from the following MS–DRGs, and to create new MS–DRGs to classify these procedures:

- MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS–DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC);
- MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS–DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC);
- MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC); and
- MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC).

The commenter stated that, historically, the MS–DRGs listed above appropriately reflected the differential cost of percutaneous transluminal coronary angioplasty (PTCA) procedures with and without stents. The commenter noted that PTCA procedures with drug eluting stents were previously paid the highest, followed by PTCA procedures with bare metal stents and PTCA procedures with no stents, respectively. However, the commenter believed that, in recent years, the opposite has begun to occur and cases reporting a PTCA procedure without a stent are being paid more than cases reporting a PTCA procedure with a stent. The commenter further noted that cardiac ablation procedures and PTCA procedures without stents are currently assigned to the same MS–DRGs, notwithstanding that the procedures have different clinical objectives and patient diagnoses. The commenter indicated that cardiac ablation procedures are performed on patients with multiple distinct cardiac arrhythmias to alter electrical conduction systems of the heart, and PTCA procedures are performed on patients with coronary atherosclerosis to open blocked coronary arteries. The commenter also noted that cardiac ablation procedures are performed in the heart chambers by cardiac electrophysiologists, require significantly more resources, and require longer periods of time to complete. Conversely, PTCA procedures are performed in the coronary vessels by interventional cardiologists, require the use of less equipment, and require a shorter period of time to complete. Therefore, the commenter suggested that CMS create new MS–DRGs for percutaneous intracardiac procedures to help improve clinical homogeneity by differentiating percutaneous intracardiac procedures (performed within the heart chambers) from percutaneous intracoronary procedures (performed within the coronary vessels). The commenter further believed that creating new MS–DRGs for these procedures would also better reflect the resource cost of specialized equipment used for more complex structures of electrical conduction systems when performing cardiac ablation procedures.

The following ICD–9–CM procedure codes identify and describe the cardiac ablation procedures and the other percutaneous intracardiac procedures that are currently classified under MS–DRGs 246 through 251 and that the commenter recommended that CMS assign to the newly created MS–DRGs:

- 35.52 (Repair of atrial septal defect with prosthesis, closed technique);
- 35.96 (Percutaneous balloon valvuloplasty);
- 35.97 (Percutaneous mitral valve repair with implant);
- 37.26 (Catheter based invasive electrophysiologic testing);
- 37.27 (Cardiac mapping);
- 37.34 (Excision or destruction of other lesion or tissue of heart, endovascular approach);
- 37.36 (Excision, destruction, or exclusion of left atrial appendage (LAA)); and
- 37.90 (Insertion of left atrial appendage device).

There are a number of ICD–10–PCS code translations that provide more detailed and specific information for each of the ICD–9–CM procedure codes listed above that also are currently classified under MS–DRGs 246 through 251 based on the GROUPER Version 32 ICD–10 MS–DRGs. The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 35.52 are shown in the following table.

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 35.52

ICD–10–PCS Code	Code description
02U53JZ	Supplement atrial septum with synthetic substitute, percutaneous approach.
02U54JZ	Supplement atrial septum with synthetic substitute, percutaneous endoscopic approach.

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 35.96 are shown in the following table.

ICD–10–PCS TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.96

ICD–10–PCS Code	Code description
027F34Z	Dilation of aortic valve with drug-eluting intraluminal device, percutaneous approach.
027F3DZ	Dilation of aortic valve with intraluminal device, percutaneous approach.
027F3ZZ	Dilation of aortic valve, percutaneous approach.
027F44Z	Dilation of aortic valve with drug-eluting intraluminal device, percutaneous endoscopic approach.
027F4DZ	Dilation of aortic valve with intraluminal device, percutaneous endoscopic approach.
027F4ZZ	Dilation of aortic valve, percutaneous endoscopic approach.
027G34Z	Dilation of mitral valve with drug-eluting intraluminal device, percutaneous approach.
027G3DZ	Dilation of mitral valve with intraluminal device, percutaneous approach.
027G3ZZ	Dilation of mitral valve, percutaneous approach.
027G44Z	Dilation of mitral valve with drug-eluting intraluminal device, percutaneous endoscopic approach.
027G4DZ	Dilation of mitral valve with intraluminal device, percutaneous endoscopic approach.
027G4ZZ	Dilation of mitral valve, percutaneous endoscopic approach.
027H34Z	Dilation of pulmonary valve with drug-eluting intraluminal device, percutaneous approach.
027H3DZ	Dilation of pulmonary valve with intraluminal device, percutaneous approach.
027H3ZZ	Dilation of pulmonary valve, percutaneous approach.
027H44Z	Dilation of pulmonary valve with drug-eluting intraluminal device, percutaneous endoscopic approach.
027H4DZ	Dilation of pulmonary valve with intraluminal device, percutaneous endoscopic approach.
027H4ZZ	Dilation of pulmonary valve, percutaneous endoscopic approach.
027J34Z	Dilation of tricuspid valve with drug-eluting intraluminal device, percutaneous approach.
027J3DZ	Dilation of tricuspid valve with intraluminal device, percutaneous approach.
027J3ZZ	Dilation of tricuspid valve, percutaneous approach.
027J44Z	Dilation of tricuspid valve with drug-eluting intraluminal device, percutaneous endoscopic approach.
027J4DZ	Dilation of tricuspid valve with intraluminal device, percutaneous endoscopic approach.
027J4ZZ	Dilation of tricuspid valve, percutaneous endoscopic approach.

The ICD–10–PCS code translation for ICD–9–CM procedure code 35.97 is 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach).

The ICD–10–PCS code translation for ICD–9–CM procedure code 37.26 is 4A023FZ (Measurement of cardiac rhythm, percutaneous approach).

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.27 are shown in the following table.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.27

ICD–10–PCS Code	Code description
02K83ZZ	Map conduction mechanism, percutaneous approach.
02K84ZZ	Map conduction mechanism, percutaneous endoscopic approach.

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.34 are shown in the following table:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.34

ICD–10–PCS Code	Code description
02553ZZ	Destruction of atrial septum, percutaneous approach.
02563ZZ	Destruction of right atrium, percutaneous approach.
02573ZZ	Destruction of left atrium, percutaneous approach.
02583ZZ	Destruction of conduction mechanism, percutaneous approach.
02593ZZ	Destruction of chordae tendineae, percutaneous approach.
025F3ZZ	Destruction of aortic valve, percutaneous approach.
025G3ZZ	Destruction of mitral valve, percutaneous approach.
025H3ZZ	Destruction of pulmonary valve, percutaneous approach.
025J3ZZ	Destruction of tricuspid valve, percutaneous approach.
025K3ZZ	Destruction of right ventricle, percutaneous approach.
025L3ZZ	Destruction of left ventricle, percutaneous approach.
025M3ZZ	Destruction of ventricular septum, percutaneous approach.
02B53ZZ	Excision of atrial septum, percutaneous approach.
02B63ZZ	Excision of right atrium, percutaneous approach.
02B73ZZ	Excision of left atrium, percutaneous approach.
02B83ZZ	Excision of conduction mechanism, percutaneous approach.
02B93ZZ	Excision of chordae tendineae, percutaneous approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.34—Continued

ICD–10–PCS Code	Code description
02BF3ZZ	Excision of aortic valve, percutaneous approach.
02BG3ZZ	Excision of mitral valve, percutaneous approach.
02BH3ZZ	Excision of pulmonary valve, percutaneous approach.
02BJ3ZZ	Excision of tricuspid valve, percutaneous approach.
02BM3ZZ	Excision of ventricular septum, percutaneous approach.
02T83ZZ	Resection of conduction mechanism, percutaneous approach.

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.36 are shown in the following table:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.36

ICD–10–PCS Code	Code description
02573ZK	Destruction of left atrial appendage, percutaneous approach.
02574ZK	Destruction of left atrial appendage, percutaneous endoscopic approach.
02B73ZK	Excision of left atrial appendage, percutaneous approach.
02B74ZK	Excision of left atrial appendage, percutaneous endoscopic approach.
02L73ZK	Occlusion of left atrial appendage, percutaneous approach.
02L74ZK	Occlusion of left atrial appendage, percutaneous endoscopic approach.

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.90 are shown in the following table:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.90

ICD–10–PCS Code	Code description
02L73CK	Occlusion of left atrial appendage with extraluminal device, percutaneous approach.
02L73DK	Occlusion of left atrial appendage with intraluminal device, percutaneous approach.
02L74CK	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic approach.
02L74DK	Occlusion of left atrial appendage with intraluminal device, percutaneous endoscopic approach.

The ICD–10–PCS code translations listed above, along with their respective MS–DRG assignments, can be found in the ICD–10 MS–DRGs Version 32 Definitions Manual posted on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*.

As mentioned earlier, we received a separate, but related, request to add severity levels to MS–DRGs 246 through 251. We address this request at the end of this section.

To address the first of these separate, but related, requests, we reviewed claims data for MS–DRGs 246 through 251 from the December 2014 update of the FY 2014 MedPAR file. Our findings are shown in the following table:

PERCUTANEOUS CARDIOVASCULAR MS–DRGS WITH AND WITHOUT STENTS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 246—All cases	30,617	5.52	$23,855
MS–DRG 246—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	244	9.69	34.099
MS–DRG 247—All cases	79,639	2.69	15,671
MS–DRG 247—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	260	5.20	25,797
MS–DRG 248—All cases	9,310	6.37	22,504
MS–DRG 248—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	125	10.76	33,521
MS–DRG 249—All cases	16,273	3.08	14,066
MS–DRG 249—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	81	5.12	23,710
MS–DRG 250—All cases	9,275	7.07	22,902
MS–DRG 250—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	5,826	7.90	24,841
MS–DRG 251—All cases	20,945	3.25	15,757

PERCUTANEOUS CARDIOVASCULAR MS–DRGS WITH AND WITHOUT STENTS—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 251—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	14,436	3.39	17,290

As shown in the table above, there were a total of 30,617 cases in MS–DRG 246, with an average length of stay of 5.52 days and average costs of $23,855. For cases reporting a percutaneous intracardiac procedure in MS–DRG 246 (ICD–9–CM procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90), there were a total of 244 cases, with an average length of stay of 9.69 days and average costs of $34,099. For MS–DRGs 247 through 251, a similar pattern was identified; the data reflected that the average costs are higher and the average length of stay is greater for cases reporting a percutaneous intracardiac procedure in comparison to the average costs and average length of stay for all of the cases in their respective MS–DRGs.

As reflected in the following table, a further analysis of the data showed that percutaneous intracardiac procedures represent a total of 20,972 cases in MS–DRGs 246 through 251, with a greater average length of stay (4.79 days versus 3.62 days) and higher average costs ($19,810 versus $17,532) in comparison to all of the remaining cases in MS–DRGs 246 through 251.

SUMMARY OF PERCUTANEOUS CARDIOVASCULAR DRGS WITH AND WITHOUT STENTS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 246 through 251—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	20,972	4.79	$19,810
MS–DRGs 246 through 251—Cases without procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	145,087	3.62	17,532

We stated in the FY 2016 IPPS/LTCH PPS proposed rule that the results of these data analyses support removing procedures performed within the heart chambers using intracardiac techniques from MS–DRGs 246 through 251, and assigning these procedures to separate MS–DRGs. The results of these data analyses also supported subdividing these MS–DRGs using the ''with MCC'' and ''without MCC'' severity levels based on the application of the criteria established in the FY 2008 IPPS final rule (72 FR 47169), and described in section II.G.1.b. of the preamble of the proposed rule, that must be met to warrant the creation of a CC or an MCC subgroup within a base MS–DRG. Our clinical advisors also agreed that this differentiation would improve the clinical homogeneity of these MS–DRGs by separating percutaneous intracardiac procedures (performed within the heart chambers) from percutaneous intracoronary procedures (performed within the coronary vessels). In addition, we believe that creating these new MS–DRGs would better reflect the resource cost of specialized equipment used to perform more complex structures of electrical conduction systems during cardiac ablation procedures. Therefore, for FY 2016, we proposed to create two new MS–DRGs to classify percutaneous intracardiac procedures (80 FR24359). Specifically, we proposed to create MS–DRG 273, entitled ''Percutaneous Intracardiac Procedures with MCC,'' and MS–DRG 274, entitled ''Percutaneous Intracardiac Procedures without MCC,'' and to assign the procedures performed within the heart chambers using intracardiac techniques to the two proposed new MS–DRGs. We proposed that existing percutaneous intracoronary procedures with and without stents continue to be assigned to the other MS–DRGs to reflect that those procedures are performed within the coronary vessels and require fewer resources.

The table below represents the distribution of cases, average length of stay, and average costs for these proposed two new MS–DRGs.

PROPOSED NEW MS–DRGS FOR PERCUTANEOUS INTRACARDIAC PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
Proposed MS–DRG 273 with MCC	6,195	8.03	$25,380
Proposed MS–DRG 274 without MCC	14,777	3.44	17,475

We invited public comments on our proposal to create the two new MS–DRGs for percutaneous intracardiac procedures for FY 2016. In addition, we invited public comments on the ICD–10–PCS code translations that were presented earlier in this section and our proposal to assign these procedure codes to the proposed new MS–DRGs 273 and 274.

Comment: Several commenters supported the proposal to create proposed new MS–DRG 273 and MS–DRG 274 to improve clinical homogeneity and better reflect resource costs. The commenters stated that the proposal was reasonable, given the data and information provided. The commenters also agreed with the proposed ICD–10–PCS code translations and assignment of those codes to the proposed new MS–DRGs.

Several commenters commended CMS for conducting the analysis and continuing to make further refinements to the MS–DRGs. One commenter specifically expressed appreciation for CMS' display of cost and length of stay data in the analysis, in addition to the clinical factors that support

differentiation of intracardiac procedures from intracoronary procedures. This commenter recommended that, if the two proposed MS–DRGs are finalized, CMS continue to monitor them after ICD–10 implementation in an effort to mitigate potential unintended consequences. The commenter also suggested that, in the future, additional procedure codes may warrant assignment to the proposed new MS–DRGs. Another commenter stated that adopting the proposal to create the new MS–DRGs will lead to more appropriate payment.

Response: We appreciate the commenters' support. We agree that creating these new MS–DRGs will better reflect utilization of resources and clinical cohesiveness for intracardiac procedures in comparison to intracoronary procedures, as well as provide for appropriate payment for the procedures.

Comment: One commenter supported the proposal but also requested that CMS provide additional information on how the payment rate will be adjusted for the remaining existing MS–DRGs (246 through 251) following the creation of proposed new MS–DRGs 273 and 274.

Response: We thank the commenter for its support. For payment rate updates to all of the MS–DRGs for FY 2016, we refer readers to Table 5 associated with this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

After consideration of the public comments we received, we are finalizing our proposal to create MS–DRGs 273 (Percutaneous Intracardiac Procedures with MCC) and MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC) for the FY 2016 ICD–10 MS–DRGs Version 33.

As mentioned earlier in this section, we received a similar request in response to the FY 2015 IPPS/LTCH PPS proposed rule to add severity levels to MS–DRGs 246 through 251. We considered this public comment to be outside of the scope of the FY 2015 IPPS/LTCH PPS proposed rule. Therefore, we did not address this comment in the FY 2015 IPPS/LTCH PPS final rule. However, we indicated that we would consider the public comment for possible proposals in future rulemaking as part of our annual review process. Specifically, the commenter recommended including additional severity levels for MS–DRGs 246 through 251 and establishing severity levels for MS–DRG 245 (AICD Generator Procedures).

For our data analysis for this recommendation, we examined claims data from the December 2014 update of the FY 2014 MedPAR file to determine if including additional severity levels in MS–DRGs 246 through 251 was warranted. During our analysis, we applied the criteria established in the FY 2008 IPPS final rule (72 FR 47169), as described in section II.G.1.b. of the preamble of the proposed rule. As shown in the table below, we collapsed MS–DRGs 246 through 251 into base MS–DRGs (MS–DRGs 246, 248, and 250) by suggested severity level and applied the criteria.

PERCUTANEOUS CARDIOVASCULAR MS–DRG WITH AND WITHOUT STENT PROCEDURES BY SUGGESTED SEVERITY LEVEL

MS–DRG	Number of cases	Average length of stay	Average costs
Suggested MS–DRG 246 with MCC	30,617	5.52	$23,855
Suggested MS–DRG 246 with CC	45,313	2.96	16,233
Suggested MS–DRG 246 without CC/MCC	34,326	2.33	14,928
Suggested MS–DRG 248 with MCC	9,310	6.37	22,504
Suggested MS–DRG 248 with CC	9,510	3.49	14,798
Suggested MS–DRG 248 without CC/MCC	6,763	2.51	13,037
Suggested MS–DRG 250 with MCC	9,275	7.07	22,903
Suggested MS–DRG 250 with CC	11,653	3.80	16,113
Suggested MS–DRG 250 without CC/MCC	9,292	2.56	15,310

We found that the criterion that there be a $2,000 difference in average costs between subgroups was not met. Specifically, between the ''with CC'' and ''without CC/MCC'' subgroups for base MS–DRG 246, the difference in average costs was only $1,305; for base MS–DRG 248, the difference in average costs was only $1,761; and for base MS–DRG 250, the difference in average costs was only $803. The results of the data analysis of MS–DRGs 246 through 251 confirmed, and our clinical advisors agreed, that the existing 2-way severity level splits for these MS–DRGs (with MCC and without MCC) are appropriate, as displayed in the table below.

PERCUTANEOUS CARDIOVASCULAR MS–DRGS WITH AND WITHOUT STENTS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 246—All cases	30,617	5.52	$23,855
MS–DRG 247—All cases	79,639	2.69	15,671
MS–DRG 248—All cases	9,310	6.37	22,504
MS–DRG 249—All cases	16,273	3.08	14,066
MS–DRG 250—All cases	9,275	7.07	22,903
MS–DRG 251—All cases	20,945	3.25	15,757

Therefore, we did not propose to further subdivide the severity levels for MS–DRGs 246 through 251. We invited public comments on our proposal not to create additional severity levels for MS–DRGs 246 through 251.

Comment: Several commenters supported the proposal not to create additional severity levels for MS–DRGs 246 through 251. The commenters stated that the proposal was reasonable,

given the data and information provided.

Response: We appreciate the commenters' support. Therefore, we are finalizing our proposal to not create additional severity levels for MS–DRGs 246–251 for the FY 2016 ICD–10 MS–DRGs Version 33.

Using the same MedPAR claims data for FY 2014, we separately examined cases in MS–DRG 245 to determine whether to subdivide this MS–DRG into severity levels. As displayed in the table below, the results of the FY 2014 data analysis showed there were a total of 1,699 cases, with an average length of stay of 5.49 days and average costs of $34,287, in MS–DRG 245.

AICD GENERATOR PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 245—All cases	1,699	5.49	$34,287

We applied the five criteria established in the FY 2008 IPPS final rule (72 FR 47169), as described in section II.G.1.b. of the preamble of the proposed rule, to determine if it was appropriate to subdivide MS–DRG 245 into severity levels. The table below illustrates our findings.

AICD Generator procedures by suggested severity level	Number of cases	Average length of stay	Average costs
Suggested MS–DRG 245 with MCC	542	8.15	$40,004
Suggested MS–DRG 245 with CC	939	4.51	$32,237
Suggested MS–DRG 245 without CC/MCC	218	3.12	$28,907

Based on the analysis of the FY 2014 claims data for MS–DRG 245, the results supported creating a ''with MCC'' and a ''without MCC'' severity level split. However, our clinical advisors indicated that it would not be clinically appropriate to add severity levels based on an isolated year's data fluctuation because this could lead to a lack of stability in MS–DRG payments. We agreed with our clinical advisors and noted that we annually conduct an analysis of base MS–DRGs to evaluate if additional severity levels are warranted. This analysis includes 2 years of MedPAR claims data to specifically compare data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation. Generally, in past years, for our review of requests to add or establish severity levels, in our analysis of the most recent claims data, there was at least one criterion that was not met. Therefore, it was not necessary to further analyze data beyond 1 year. However, the results of our analysis of claims data in the December 2014 update of the FY 2014 MedPAR file for this particular request involving MS–DRG 245 demonstrate that all five criteria to establish subgroups were met, and, therefore, it was necessary to also examine the FY 2013 MedPAR claims data file.

The results of our analysis from the December 2013 update of the FY 2013 claims data for MS–DRG 245 are shown in the table below.

AICD GENERATOR PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 245—All cases	1,850	4.81	$33,272

The FY 2013 claims data for MS–DRG 245 did not support creating any severity levels because the data did not meet one or more of the five required criteria for creating new severity levels. The data did not meet the requirement for a 3-way severity level split (with MCC, with CC, and without CC/MCC) or a 2-way severity level split (with MCC and without MCC) because there were not at least 500 cases in the MCC subgroup. While the data did meet this particular criterion for the 2-way severity level split of ''with CC/MCC'' and ''without CC/MCC'' because there were at least 500 cases in the CC subgroup, the data did not meet the criterion that there be at least a 20-percent difference in average costs between subgroups, as shown in the table below.

AICD GENERATOR PROCEDURES

MS–DRG by suggested severity level	Number of cases	Average length of stay	Average costs
MS–DRG 245 with MCC	44	7.32	$39,536
MS–DRG 245 with CC	1,118	4.26	$31,786
MS–DRG 245 without CC/MCC	288	3.10	$29,383

As stated previously, we believe that 2 years of data showing that the requested CC or MCC subgroup meets all five of the established criteria for creating severity levels are needed in order to support a proposal to add

severity levels for MS–DRG 245. Our clinical advisors also agreed that it would not be clinically appropriate to add severity levels based on an isolated year's data fluctuation because this could lead to a lack of stability in payments. Therefore, we did not propose to add severity levels for MS–DRG 245 for FY 2016. We invited public comments on the results of our analysis and our proposal not to create severity levels for MS–DRG 245.

Comment: Several commenters supported the proposal not to create severity levels for MS–DRG 245. The commenters stated that the proposal was reasonable, given the data and information provided. One commenter specifically noted that it understood the rationale of CMS' proposal based on analysis of the FY 2013 and FY 2014 data fluctuation. However, the commenter recommended that a followup analysis be conducted for the FY 2017 IPPS/LTCH PPS proposed rule.

Response: We appreciate the commenters' support. We intend to conduct a followup analysis for MS–DRG 245 in the FY 2017 IPPS/LTCH PPS proposed rule as the commenter recommended.

After consideration of the public comments we received, we are finalizing our proposal not to create severity levels for MS–DRG 245 in FY 2016.

c. Zilver® PTX Drug-Eluting Peripheral Stent (Zilver® PTX®)

The Zilver® PTX Drug-Eluting Peripheral Stent (Zilver® PTX®) was approved for new technology add-on payments in FY 2014 (78 FR 50583 through 50585). Cases involving the Zilver® PTX® that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 00.60 (Insertion of drug-eluting stent(s) of superficial femoral artery).

We received a request from the manufacturer for an extension of new technology add-on payments for Zilver® PTX® in FY 2016. In the request, the manufacturer asked CMS to consider three options for procedure code 00.60 for FY 2016. The first option was to extend the new technology add-on payment through FY 2016. The request to extend the new technology add-on payment is addressed in section II.I.3.e. of the preamble of the proposed rule and this final rule. The second option was to establish a new family of MS–DRGs for procedures involving drug-eluting stents used in the peripheral (noncoronary) vasculature. The third option was to assign all Zilver® PTX® cases to MS–DRG 252 even if there is no MCC (which would necessitate revising the MS–DRG title to ''Other Vascular Procedures).

ICD–10–PCS provides the following more detailed procedure codes for the insertion of drug-eluting stents of superficial femoral artery:

- 047K04Z (Dilation of right femoral artery with drug-eluting intraluminal device, open approach);
- 047K34Z (Dilation of right femoral artery with drug-eluting intraluminal device, percutaneous approach);
- 047K44Z (Dilation of right femoral artery with drug-eluting intraluminal device, percutaneous endoscopic approach);
- 047L04Z (Dilation of left femoral artery with drug-eluting intraluminal device, open approach);
- 047L34Z (Dilation of left femoral artery with drug-eluting intraluminal device, percutaneous approach); and
- 047L44Z (Dilation of left femoral artery with drug-eluting intraluminal device, percutaneous endoscopic approach).

We examined claims data for cases involving the drug-eluting peripheral stent procedures reported in the December 2014 update of the FY 2014 MedPAR file for MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC and without CC/MCC, respectively). The following table illustrates our findings.

DRUG-ELUTING PERIPHERAL STENT PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 252—All cases	30,696	7.89	$23,935
MS–DRG 252—Cases with procedure code 00.60	133	9.08	32,623
MS–DRG 253—All cases	34,746	5.68	19,030
MS–DRG 253—Cases with procedure code 00.60	353	4.99	25,396
MS–DRG 254—All cases	15,394	2.99	12,629
MS–DRG 254—Cases with procedure code 00.60	115	2.62	21,461

Our findings showed that there were only 601 peripheral angioplasty cases with a drug-eluting stent reported. Of the 601 peripheral angioplasty cases with a drug-eluting stent, 133 cases were in MS–DRG 252, 353 cases were in MS–DRG 253, and 115 cases were in MS–DRG 254. The average costs for the drug-eluting stent cases in MS–DRGs 252, 253, and 254 were $32,623, $25,396, and $21,461, respectively. The average costs for all cases in MS–DRGs 252, 253, and 254 were $23,935, $19,030, and $12,629, respectively. The average costs for the drug-eluting stent cases in MS–DRG 253 ($25,396) were higher than the average costs for all cases in MS–DRG 252 ($23,935). However, the average costs for the drug-eluting stent cases in MS–DRG 254 ($21,461) were lower than the average costs for all cases in MS–DRG 252 ($23,935).

We determined that the small number of cases (601) did not provide justification to create a new set of MS–DRGs specifically for angioplasty of peripheral arteries using drug-eluting stents. In addition, the data did not support assigning all the drug-eluting stent cases to the highest severity level (MS–DRG 252), even when there is not an MCC, because the average costs for the drug-eluting stent cases in MS–DRG 254 ($21,461) were lower than the average costs for all cases in MS–DRG 252 ($23,935). The average length of stay for drug-eluting stent cases in MS–DRG 254 was 2.62 days compared to 7.89 days for all cases in MS–DRG 252. Cases are grouped together based on similar clinical and resource criteria.

Our clinical advisors recommended making no MS–DRG updates for peripheral angioplasty cases with a drug-eluting stent and considered the current MS–DRG assignment appropriate. Our clinical advisors agreed that the small number of peripheral angioplasty cases with a drug-eluting stent does not support creating a new MS–DRG for this specific type of treatment. They stated that the cases are clinically similar to other cases within MS–DRGs 252, 253, and 254. Considering the data for peripheral angioplasty cases with a drug-eluting stent found reported in MS–DRGs 252, 253, and 254 and the input from our clinical advisors, in the FY 2016 IPPS/

LTCH proposed rule (80 FR 24362), we did not propose to make any MS–DRG updates for peripheral angioplasty cases with a drug-eluting stent. We proposed to maintain the current MS–DRG assignments for these cases in MS–DRGs 252, 253, and 254. We invited public comments on our proposal.

Comment: A number of commenters supported the proposal to maintain the current MS–DRG assignments for peripheral angioplasty cases with a drug-eluting stent in MS–DRGs 252, 253, and 254. The commenters stated that the proposal was reasonable, given the data and information provided.

One commenter, the manufacturer, expressed concern with the proposal and asked CMS to reconsider its recommendation for denying the request that all Zilver® PTX® cases be assigned to MS–DRG 252 even if there were no MCC. The commenter stated that it is true that assignment of all drug-eluting cases to MS–DRG 252 would result in an overpayment for cases with a drug-eluting stent that currently are assigned to MS–DRG 254. However, the commenter stated that these cases represent only 19 percent of the drug-eluting stent cases, and that the overpayment of these cases would be modest because the average cost of drug-eluting stent cases in MS–DRG 254 is only $2,500 less than the average cost of all cases in MS–DRG 252. The commenter stated that there would be an underpayment for all the drug-eluting stent cases if the cases continue to be assigned to MS–DRGs 252, 253, and 254. The commenter stated that implementing its original request would allow more adequate payment to hospitals using the Zilver® PTX® technology and thus remove a potential financial barrier to Medicare providers desiring to provide access of this technology to their patients.

Another commenter asserted that it understood CMS' concern that the agency could be overpaying for uncomplicated cases by assigning all drug-eluting stent cases to MS–DRG 252, even if they did not have a MCC. However, the commenter stated that CMS is underpaying all drug-eluting stent cases by maintaining the current MS–DRG assignments for these procedures. The commenter expressed concern regarding patient access to this technology.

Response: We appreciate the commenters' support for our proposal to maintain the current MS–DRG for drug-eluting stent cases in MS–DRGs 252, 253, and 254. Our clinical advisors have also reexamined this issue and continue to advise us that the cases reporting procedure code 00.60 are appropriately classified within MS–DRG 252, 253, or 254.

In regard to the commenters who disagreed with our proposal, as stated earlier, the data do not support assigning all the drug-eluting stent cases to the highest severity level (MS–DRG 252), even when there is not an MCC. We note that while the average costs for MS–DRG 254 (lowest severity level) may only represent 19 percent of the drug-eluting stent cases as shown in the table above, the MS–DRGs are comprised of a distinct structure with respect to the types of patients within each severity level. This structure is based on an organizing principle that patients at the MCC level, the highest severity level, are those patients who are generally sicker, consume an increased utilization of resources, and require more complex services. Disregarding this structure solely for the purpose of increasing payment for patients who are not similar in terms of their severity of illness and resource utilization would be inconsistent with how the MS–DRGs are otherwise defined within the classification system.

In addition, as the requester pointed out in its own comments, ''it is the nature of a MS–DRG system that there will be variations in cost between different hospitalizations that fall into the same MS–DRG or MS–DRGs—each MS–DRG will have some cases that are higher and some cases that are lower than the average costs for the entire MS–DRG.'' We believe that the higher average costs for the drug-eluting stent cases can be attributed to the cost of the device and not necessarily because the patients receiving these stents are more severely ill.

With regard to the commenters' concerns regarding patient access to the technology with the expiration of the new technology add-on payment, we would expect that hospitals that now have experience with the technology and have observed favorable clinical outcomes for their patients would nonetheless consider the technology to be worth the investment. Accordingly, we will continue to monitor cases with the Zilver® PTX® technology to determine if modifications are warranted to the MS–DRG structure in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current structure for MS–DRG assignments for procedures involving drug-eluting stents in MS–DRG 252, 253, or 254 for FY 2016.

d. Percutaneous Mitral Valve Repair System—Proposed Revision of ICD–10–PCS Version 32 Logic

We received a comment which brought to our attention that the ICD–10 MS–DRGs Version 32 assignment for ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) does not accurately replicate the ICD–9–CM MS–DRGs Version 32, which assigns this procedure code to the following MS–DRGs:

- MS–DRG 231 (Coronary Bypass with PTCA with MCC);
- MS–DRG 232 (Coronary Bypass with PTCA without MCC);
- MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC);
- MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC);
- MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC); and
- MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC).

We agree with the commenter that the ICD–10 MS–DRGs logic should be consistent with the ICD–9 MS–DRGs logic; that is, the ICD–10 MS–DRGs Version 32 should replicate the ICD–9–CM MS–DRGs Version 32. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule, for the proposed FY 2016 ICD–10 MS–DRGs Version 33, we proposed to assign ICD–10–PCS procedure code 02UG3JZ to MS–DRGs 231 and 232 and MS–DRGs 246 through 251 (80 FR 24362). We invited public comments on this proposal.

Comment: Several commenters agreed with the proposal to assign ICD–10–PCS procedure code 02UG3JZ to ICD–10 MS–DRGs 231 and 232 and MS–DRGs 246 through 251 to accurately replicate the ICD–9–CM MS–DRGs Version 32 logic. The commenters also noted that, as discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24356 through 24359), for the FY 2016 ICD–10 MS–DRGs Version 33, CMS proposed to create two new ICD–10 MS–DRGs which include ICD–10–PCS procedure code 02UG3JZ. The commenters recognized that, if proposed new MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively) were finalized for FY 2016, ICD–10–PCS procedure code 02UG3JZ would then group to those new MS–DRGs. The

commenters requested that CMS confirm the MS–DRG assignment.

Response: We appreciate the commenters' support for our proposal to accurately replicate the assignment of ICD–10–PCS procedure code 02UG3JZ under the ICD–10 MS–DRGs. As discussed earlier in section III.G.3.a. of this final rule, we are finalizing our proposal to create ICD–10 MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively). After consideration of the public comments we received, we are confirming as final policy for the FY 2016 ICD–10 MS–DRGs Version 33 that ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) is assigned to new ICD–10 MS–DRGs 273 and 274 and will continue to be assigned to MS–DRGs 231 and 232 (Coronary Bypass with PTC with MCC and without MCC, respectively).

e. Major Cardiovascular Procedures: Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Graft

New technology add-on payments for the Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Graft (Zenith® F. Graft) will end on September 30, 2015. Cases involving the Zenith® F. Graft are identified by ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) in MS–DRGs 237 and 238 (Major Cardiovascular Procedures with and without MCC, respectively). For additional information on the Zenith® F. Graft, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49921 through 49922).

We received a request to reassign procedures described by ICD–9–CM procedure code 39.78 to the highest severity level in MS–DRGs 237 and 238, including in instances when there is not an MCC present, or to create a new MS–DRG that would contain all endovascular aneurysm repair procedures. We note that, in addition to ICD–9–CM procedure code 39.78, ICD–9–CM procedure code 39.71 (Endovascular implantation of other graft in abdominal aorta) also describes endovascular aneurysm repair procedures.

There are a number of ICD–10–PCS code translations that provide more detailed and specific information for each of ICD–9–CM codes 39.71 and 39.78 that also currently group to MS–DRGs 237 and 238 in the ICD–10 MS–DRGs Version 32. The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.71 and 39.78 are shown in the following tables:

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 39.71

ICD–10–PCS Code	Code description
04U03JZ	Supplement abdominal aorta with synthetic substitute, percutaneous approach.
04U04JZ	Supplement abdominal aorta with synthetic substitute, percutaneous endoscopic approach.
04V03DZ	Restriction of abdominal aorta with intraluminal device, percutaneous approach.
04V04DZ	Restriction of abdominal aorta with intraluminal device, percutaneous endoscopic approach.

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 39.78

ICD–10–PCS Code	Code description
04V03DZ	Restriction of abdominal aorta with intraluminal device, percutaneous approach.
04V04DZ	Restriction of abdominal aorta with intraluminal device, percutaneous endoscopic approach.

Note: As discussed later in this section, the FY 2016 IPPS/LTCH PPS proposed rule listed the dilation codes ICD–10–PCS 04793DZ through 04754DZ as possible translations for ICD–9–CM procedure code 39.78. For this final rule, we are only listing those codes that as ''standalone'' procedures are assigned to new MS–DRGs 268 and 269.

We analyzed claims data reporting ICD–9–CM procedure code 39.78 for cases assigned to MS–DRGs 237 and 238 in the December 2014 update of the FY 2014 MedPAR file. We found a total of 18,340 cases, with an average length of stay of 9.46 days and average costs of $36,355 in MS–DRG 237. We found 332 cases reporting ICD–9–CM procedure code 39.78, with an average length of stay of 8.46 days and average costs of $51,397 in MS–DRG 237. For MS–DRG 238, we found a total of 32,227 cases, with an average length of stay of 3.72 days and average costs of $25,087. We found 1,927 cases reporting ICD–9–CM procedure code 39.78, with an average length of stay of 2.52 days and average costs of $31,739 in MS–DRG 238.

Zenith Fenestrated Graft Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237—All cases	18,340	9.46	$36,355
MS–DRG 237—Cases with procedure code 39.78	332	8.46	51,397
MS–DRG 238—All cases	32,227	3.72	25,087
MS–DRG 238—Cases with procedure code 39.78	1,927	2.52	31,739

As illustrated in the table above, the results of the data analysis indicate that the average costs for cases reporting procedure code 39.78 assigned to MS–DRG 238 were higher than the average costs for all cases in MS–DRG 238 ($31,739 compared to $25,087). In addition, the average costs for the 1,927 cases reporting procedure code 39.78 assigned to MS–DRG 238 were $4,616 less than the costs of all cases assigned to MS–DRG 237. We determined that moving cases reporting procedure code 39.78 from MS–DRG 238 to MS–DRG 237 would result in overpayments. We

also noted that the average length of stay for the 1,927 cases reporting procedure code 39.78 in MS–DRG 238 was 2.52 days in comparison to the average length of stay for all cases in MS–DRG 237 of 9.46 days. Our clinical advisors did not agree with moving cases reporting procedure code 39.78 to a higher severity level (with MCC) MS–DRG.

We believe that the higher average costs could be attributed to the cost of the device. The Zenith® F. Graft is the only fenestrated graft device currently approved by the FDA. Therefore, this manufacturer is able to set its own costs in the market. We pointed out that the IPPS is not designed to pay solely for the cost of devices. More importantly, moving cases that greatly differ in their severity of illness and complexity of resources into a higher severity level MS–DRG, in the absence of an MCC, would conflict with the objective of the MS–DRGs, which is to maintain homogeneous subgroups that are different from one another in terms of utilization of resources, that have enough volume to be meaningful, and that improve our ability to explain variance in resource use (72 FR 47169). Therefore, we did not propose to reassign all cases reporting procedure code 39.78 from MS–DRG 238 to MS–DRG 237, as the commenter requested.

However, we recognized that the results of the data analysis also demonstrated that the average costs for cases reporting ICD–9–CM procedure code 39.78 are higher in both MS–DRG 237 and MS–DRG 238 in comparison to all cases in each respective MS–DRG. As these higher average costs could be attributable to the cost of the device, we noted the commenter's concern that the end of the new technology add-on payment for Zenith® F. Graft, effective September 30, 2015, may result in reduced payment to hospitals and potentially lead to issues involving access to care for the subset of beneficiaries who would benefit from treatment with the Zenith® F. Graft. We continued to review the data to explore other alternatives as we analyzed additional claims data in response to the second part of the request from the commenter; that is, to create a new MS–DRG that would contain all endovascular aneurysm repair procedures.

In our evaluation of the claims data in response to the request to create a new MS–DRG, we again reviewed claims data from the December 2014 update of the FY 2014 MedPAR file. We began our analysis by examining claims data for cases reporting ICD–9–CM procedure codes 39.71 and 39.78 assigned to MS–DRGs 237 and 238. Our findings are shown in the table below.

ENDOVASCULAR ABDOMINAL AORTA PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237—All cases	18,340	9.46	$36,355
MS–DRG 237—Cases with procedure codes 39.71 and 39.78	2,425	8.34	47,363
MS–DRG 238—All cases	32,227	3.72	25,087
MS–DRG 238—Cases with procedure codes 39.71 and 39.78	16,502	2.27	28,998

As shown in the table above, the average costs for cases involving endovascular abdominal aorta aneurysm repair procedures assigned to MS–DRG 237 were higher than the average costs of all cases assigned to MS–DRGs 237. The average costs for cases reporting ICD–9–CM procedure codes 39.71 and 39.78 assigned to MS–DRG 237 were $47,363 compared to the average costs of $36,355 for all cases assigned to MS–DRG 237 and $25,087 for all cases assigned to MS–DRG 238. Similarly, the average costs for cases reporting ICD–9–CM procedure codes 39.71 and 39.78 assigned to MS–DRG 238 were higher than the average costs of all cases assigned to MS–DRG 238 ($28,998 compared to $25,087). The average length of stay for cases reporting ICD–9–CM procedure codes 39.71 and 39.78 in MS–DRGs 237 and 238 were also shorter than the average length of stay for all cases in the respective MS–DRG.

Our clinical advisors did not support creating a new MS–DRG specifically for endovascular abdominal aortic aneurysm repair procedures only. Therefore, we reviewed other procedure codes currently assigned to MS–DRGs 237 and 238 and found that there were a number of procedures with varying resource requirements and clinical indications that could be analyzed further. We agreed with our clinical advisors that further analysis was warranted to determine how we could better recognize resource utilization, clinical complexity, and average costs by separating the more complex, more invasive, and more expensive procedures used to treat more severely ill individuals from the less complex, less invasive, and less expensive procedures currently grouped to these MS–DRGs.

Therefore, we evaluated all of the procedures currently assigned to MS–DRGs 237 and 238. In our evaluation, we found that MS–DRGs 237 and 238 contained two distinct groups of procedures. We found a high volume of less invasive procedures, such as pericardiotomies and pulsation balloon implants, that had substantially lower costs than the more invasive procedures, such as open and endovascular repairs of the aorta with replacement grafts. We found that the more invasive procedures were primarily associated with procedures on the aorta and heart assist procedures.

For this next phase of our analysis, the following procedure codes were designated as the more complex, more invasive procedures:

- 37.41 (Implantation of prosthetic cardiac support device around the heart);
- 37.49 (Other repair of heart and pericardium);
- 37.55 (Removal of internal biventricular heart replacement system);
- 37.64 (Removal of external heart assist system(s) or device(s));
- 38.04 (Incision of vessel, aorta);
- 38.14 (Endarterectomy, aorta);
- 38.34 (Resection of vessel with anastomosis, aorta);
- 38.44 (Resection of vessel with replacement, aorta, abdominal);
- 38.64 (Other excision of vessels, aorta, abdominal);
- 38.84 (Other surgical occlusion of vessels, aorta, abdominal);
- 39.24 (Aorta-renal bypass);
- 39.71 (Endovascular implantation of other graft in abdominal aorta); and
- 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta).

There are a number of ICD–10–PCS code translations that provide more detailed and specific information for each of the ICD–9–CM codes listed above that also currently group to MS–DRGs 237 and 238 in the ICD–10 MS–DRGs Version 32. The comparable ICD–10–PCS code translations for these ICD–

9–CM procedure codes are shown in the following table:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.41

ICD–10–PCS Code	Code description
02UA0JZ	Supplement heart with synthetic substitute, open approach.
02UA3JZ	Supplement heart with synthetic substitute, percutaneous approach.
02UA4JZ	Supplement heart with synthetic substitute, percutaneous endoscopic approach.

For the ICD–9–CM codes that result in greater than 50 ICD–10–PCS comparable code translations, we refer readers to Table 6P (ICD–10–PCS Code Translations for MS–DRG Changes) for this FY 2016 final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). The table includes the MDC topic, the ICD–9–CM code, and the ICD–10–PCS code translations.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.49

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.49 are shown in Table 6P.1a for this final rule that is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.55

ICD–10–PCS Code	Code description
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.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.64

ICD–10–PCS Code	Code description
02PA0RZ	Removal of external heart assist system from heart, open approach.
02PA3RZ	Removal of external heart assist system from heart, percutaneous approach.
02PA4RZ	Removal of external heart assist system from heart, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.04

ICD–10–PCS Code	Code description
02CW0ZZ	Extirpation of matter from thoracic aorta, open approach.
02CW3ZZ	Extirpation of matter from thoracic aorta, percutaneous approach.
02CW4ZZ	Extirpation of matter from thoracic aorta, percutaneous endoscopic approach.
04C00ZZ	Extirpation of matter from abdominal aorta, open approach.
04C03ZZ	Extirpation of matter from abdominal aorta, percutaneous approach.
04C04ZZ	Extirpation of matter from abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.14

ICD–10–PCS Code	Code description
02CW0ZZ	Extirpation of matter from thoracic aorta, open approach.
02CW3ZZ	Extirpation of matter from thoracic aorta, percutaneous approach.
02CW4ZZ	Extirpation of matter from thoracic aorta, percutaneous endoscopic approach.
04C00ZZ	Extirpation of matter from abdominal aorta, open approach.
04C03ZZ	Extirpation of matter from abdominal aorta, percutaneous approach.
04C04ZZ	Extirpation of matter from abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.34

ICD–10–PCS Code	Code description
02BW0ZZ	Excision of thoracic aorta, open approach.
02BW4ZZ	Excision of thoracic aorta, percutaneous endoscopic approach.
04B00ZZ	Excision of abdominal aorta, open approach.
04B04ZZ	Excision of abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.44

ICD–10–PCS Code	Code description
04R007Z	Replacement of abdominal aorta with autologous tissue substitute, open approach.
04R00JZ	Replacement of abdominal aorta with synthetic substitute, open approach.
04R00KZ	Replacement of abdominal aorta with nonautologous tissue substitute, open approach.
04R047Z	Replacement of abdominal aorta with autologous tissue substitute, percutaneous endoscopic approach.
04R04JZ	Replacement of abdominal aorta with synthetic substitute, percutaneous endoscopic approach.
04R04KZ	Replacement of abdominal aorta with nonautologous tissue substitute, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.64

ICD–10–PCS Code	Code description
04500ZZ	Destruction of abdominal aorta, open approach.
04503ZZ	Destruction of abdominal aorta, percutaneous approach.
04504ZZ	Destruction of abdominal aorta, percutaneous endoscopic approach.
04B00ZZ	Excision of abdominal aorta, open approach.
04B03ZZ	Excision of abdominal aorta, percutaneous approach.
04B04ZZ	Excision of abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.84

ICD–10–PCS Code	Code description
04L00CZ	Occlusion of abdominal aorta with extraluminal device, open approach.
04L00DZ	Occlusion of abdominal aorta with intraluminal device, open approach.
04L00ZZ	Occlusion of abdominal aorta, open approach.
04L03CZ	Occlusion of abdominal aorta with extraluminal device, percutaneous approach.
04L03DZ	Occlusion of abdominal aorta with intraluminal device, percutaneous approach.
04L03ZZ	Occlusion of abdominal aorta, percutaneous approach.
04L04CZ	Occlusion of abdominal aorta with extraluminal device, percutaneous endoscopic approach.
04L04DZ	Occlusion of abdominal aorta with intraluminal device, percutaneous endoscopic approach.
04L04ZZ	Occlusion of abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.24

ICD–10–PCS Code	Code description
0410093	Bypass abdominal aorta to right renal artery with autologous venous tissue, open approach.
0410094	Bypass abdominal aorta to left renal artery with autologous venous tissue, open approach.
0410095	Bypass abdominal aorta to bilateral renal artery with autologous venous tissue, open approach.
04100A3	Bypass abdominal aorta to right renal artery with autologous arterial tissue, open approach.
04100A4	Bypass abdominal aorta to left renal artery with autologous arterial tissue, open approach.
04100A5	Bypass abdominal aorta to bilateral renal artery with autologous arterial tissue, open approach.
04100J3	Bypass abdominal aorta to right renal artery with synthetic substitute, open approach.
04100J4	Bypass abdominal aorta to left renal artery with synthetic substitute, open approach.
04100J5	Bypass abdominal aorta to bilateral renal artery with synthetic substitute, open approach.
04100K3	Bypass abdominal aorta to right renal artery with nonautologous tissue substitute, open approach.
04100K4	Bypass abdominal aorta to left renal artery with nonautologous tissue substitute, open approach.
04100K5	Bypass abdominal aorta to bilateral renal artery with nonautologous tissue substitute, open approach.
04100Z3	Bypass abdominal aorta to right renal artery, open approach.
04100Z4	Bypass abdominal aorta to left renal artery, open approach.
04100Z5	Bypass abdominal aorta to bilateral renal artery, open approach.
0410493	Bypass abdominal aorta to right renal artery with autologous venous tissue, percutaneous endoscopic approach.
0410494	Bypass abdominal aorta to left renal artery with autologous venous tissue, percutaneous endoscopic approach.
0410495	Bypass abdominal aorta to bilateral renal artery with autologous venous tissue, percutaneous endoscopic approach.
04104A3	Bypass abdominal aorta to right renal artery with autologous arterial tissue, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.24—Continued

ICD–10–PCS Code	Code description
04104A4	Bypass abdominal aorta to left renal artery with autologous arterial tissue, percutaneous endoscopic approach.
04104A5	Bypass abdominal aorta to bilateral renal artery with autologous arterial tissue, percutaneous endoscopic approach.
04104J3	Bypass abdominal aorta to right renal artery with synthetic substitute, percutaneous endoscopic approach.
04104J4	Bypass abdominal aorta to left renal artery with synthetic substitute, percutaneous endoscopic approach.
04104J5	Bypass abdominal aorta to bilateral renal artery with synthetic substitute, percutaneous endoscopic approach.
04104K3	Bypass abdominal aorta to right renal artery with nonautologous tissue substitute, percutaneous endoscopic approach
04104K4	Bypass abdominal aorta to left renal artery with nonautologous tissue substitute, percutaneous endoscopic approach.
04104K5	Bypass abdominal aorta to bilateral renal artery with nonautologous tissue substitute, percutaneous endoscopic approach.
04104Z3	Bypass abdominal aorta to right renal artery, percutaneous endoscopic approach.
04104Z4	Bypass abdominal aorta to left renal artery, percutaneous endoscopic approach.
04104Z5	Bypass abdominal aorta to bilateral renal artery, percutaneous endoscopic approach

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.71

ICD–10–PCS Code	Code description
04U03JZ	Supplement abdominal aorta with synthetic substitute, percutaneous approach.
04U04JZ	Supplement abdominal aorta with synthetic substitute, percutaneous endoscopic approach.
04V03DZ	Restriction of abdominal aorta with intraluminal device, percutaneous approach.
04V04DZ	Restriction of abdominal aorta with intraluminal device, percutaneous endoscopic approach

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.78

ICD–10–PCS Code	Code description
04793DZ	Dilation of right renal artery with intraluminal device, percutaneous approach.
04794DZ	Dilation of right renal artery with intraluminal device, percutaneous endoscopic approach.
047A3DZ	Dilation of left renal artery with intraluminal device, percutaneous approach.
047A4DZ	Dilation of left renal artery with intraluminal device, percutaneous endoscopic approach.
04753DZ	Dilation of superior mesenteric artery with intraluminal device, percutaneous approach.
04754DZ	Dilation of superior mesenteric artery with intraluminal device, percutaneous endoscopic approach.
04U03JZ	Supplement abdominal aorta with synthetic substitute, percutaneous approach.
04U04JZ	Supplement abdominal aorta with synthetic substitute, percutaneous endoscopic approach.
04V03DZ	Restriction of abdominal aorta with intraluminal device, percutaneous approach.
04V04DZ	Restriction of abdominal aorta with intraluminal device, percutaneous endoscopic approach.

For the next phase of our analysis, the procedure codes shown in the following table were designated as the less complex, less invasive procedures.

ICD–9–CM PROCEDURE CODES THAT WERE DESIGNATED AS THE LESS COMPLEX, LESS INVASIVE PROCEDURES

ICD–9–CM Procedure code	Code description
35.00	Closed heart valvotomy, unspecified valve.
35.01	Closed heart valvotomy, aortic valve.
35.02	Closed heart valvotomy, mitral valve.
35.03	Closed heart valvotomy, pulmonary valve.
35.04	Closed heart valvotomy, tricuspid valve.
37.12	Pericardiotomy.
37.24	Biopsy of pericardium.
37.31	Pericardiectomy.
37.61	Implant of pulsation balloon.
37.67	Implantation of cardiomyostimulation system.
37.91	Open chest cardiac massage.
37.99	Other operations on heart and pericardium.
38.05	Incision of vessel, other thoracic vessels.
38.06	Incision of vessel, abdominal arteries.
38.07	Incision of vessel, abdominal veins.
38.15	Endarterectomy, other thoracic vessels.
38.16	Endarterectomy, abdominal arteries.
38.35	Resection of vessel with anastomosis, other thoracic vessels.
38.36	Resection of vessel with anastomosis, abdominal arteries.
38.37	Resection of vessel with anastomosis, abdominal veins.
38.46	Resection of vessel with replacement, abdominal arteries.

ICD–9–CM PROCEDURE CODES THAT WERE DESIGNATED AS THE LESS COMPLEX, LESS INVASIVE PROCEDURES—Continued

ICD–9–CM Procedure code	Code description
38.47	Resection of vessel with replacement, abdominal veins.
38.55	Ligation and stripping of varicose veins, other thoracic vessels.
38.65	Other excision of vessels, thoracic vessels.
38.66	Other excision of vessels, abdominal arteries.
38.67	Other excision of vessels, abdominal veins.
38.85	Other surgical occlusion of vessels, thoracic vessels.
38.86	Other surgical occlusion of vessels, abdominal arteries.
38.87	Other surgical occlusion of vessels, abdominal veins.
39.0	Systemic to pulmonary artery shunt.
39.1	Intra-abdominal venous shunt.
39.21	Caval-pulmonary artery anastomosis.
39.22	Aorta-subclavian-carotid bypass.
39.23	Other intrathoracic vascular shunt or bypass.
39.25	Aorta-iliac-femoral bypass.
39.26	Other intra-abdominal vascular shunt or bypass.
39.52	Other repair of aneurysm.
39.54	Re-entry operation (aorta).
39.72	Endovascular (total) embolization or occlusion of head and neck vessels.
39.75	Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils.
39.76	Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils.
39.79	Other endovascular procedures on other vessels.

There are a number of ICD–10–PCS code translations that provide more detailed and specific information for each of the ICD–9–CM codes listed in the table immediately above that also currently group to MS–DRGs 237 and 238 in the ICD–10 MS–DRGs Version 32. The comparable ICD–10–PCS code translations for these ICD–9–CM procedure codes are shown in the following tables:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.00

ICD–10–PCS Procedure code	Code description
02NF3ZZ	Release aortic valve, percutaneous approach.
02NF4ZZ	Release aortic valve, percutaneous endoscopic approach.
02NG3ZZ	Release mitral valve, percutaneous approach.
02NG4ZZ	Release mitral valve, percutaneous endoscopic approach.
02NH3ZZ	Release pulmonary valve, percutaneous approach.
02NH4ZZ	Release pulmonary valve, percutaneous endoscopic approach.
02NJ3ZZ	Release tricuspid valve, percutaneous approach.
02NJ4ZZ	Release tricuspid valve, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.01

ICD–10–PCS Procedure code	Code description
02CF3ZZ	Extirpation of matter from aortic valve, percutaneous approach.
02CF4ZZ	Extirpation of matter from aortic valve, percutaneous endoscopic approach.
02NF3ZZ	Release aortic valve, percutaneous approach.
02NF4ZZ	Release aortic valve, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.02

ICD–10–PCS Procedure code	Code description
02CG3ZZ	Extirpation of matter from mitral valve, percutaneous approach.
02CG4ZZ	Extirpation of matter from mitral valve, percutaneous endoscopic approach.
02NG3ZZ	Release mitral valve, percutaneous approach.
02NG4ZZ	Release mitral valve, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.03

ICD–10–PCS Code	Code description
02CH3ZZ	Extirpation of matter from pulmonary valve, percutaneous approach.
02CH4ZZ	Extirpation of matter from pulmonary valve, percutaneous endoscopic approach.
02NH3ZZ	Release Pulmonary Valve, Percutaneous Approach.
02NH4ZZ	Release Pulmonary Valve, Percutaneous Endoscopic Approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.04

ICD–10–PCS Code	Code description
02CJ3ZZ	Extirpation of matter from tricuspid valve, percutaneous approach.
02CJ4ZZ	Extirpation of matter from tricuspid valve, percutaneous endoscopic approach.
02NJ3ZZ	Release tricuspid valve, percutaneous approach.
02NJ4ZZ	Release tricuspid valve, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.12

ICD–10–PCS Code	Code description
02CN0ZZ	Extirpation of matter from pericardium, open approach.
02CN3ZZ	Extirpation of matter from pericardium, percutaneous approach.
02CN4ZZ	Extirpation of matter from pericardium, percutaneous endoscopic approach.
02HN00Z	Insertion of pressure sensor monitoring device into pericardium, open approach.
02HN02Z	Insertion of monitoring device into pericardium, open approach.
02HN30Z	Insertion of pressure sensor monitoring device into pericardium, percutaneous approach.
02HN32Z	Insertion of monitoring device into pericardium, percutaneous approach.
02HN40Z	Insertion of pressure sensor monitoring device into pericardium, percutaneous endoscopic approach.
02HN42Z	Insertion of monitoring device into pericardium, percutaneous endoscopic approach.
02NN0ZZ	Release pericardium, open approach.
02NN3ZZ	Release pericardium, percutaneous approach.
02NN4ZZ	Release pericardium, percutaneous endoscopic approach.
0W9D00Z	Drainage of pericardial cavity with drainage device, open approach.
0W9D0ZX	Drainage of pericardial cavity, open approach, diagnostic.
0W9D0ZZ	Drainage of pericardial cavity, open approach.
0WCD0ZZ	Extirpation of matter from pericardial cavity, open approach.
0WCD3ZZ	Extirpation of matter from pericardial cavity, percutaneous approach.
0WCD4ZZ	Extirpation of matter from pericardial cavity, percutaneous endoscopic approach.
0WHD03Z	Insertion of infusion device into pericardial cavity, open approach.
0WHD0YZ	Insertion of other device into pericardial cavity, open approach.
0WHD33Z	Insertion of infusion device into pericardial cavity, percutaneous approach.
0WHD3YZ	Insertion of other device into pericardial cavity, percutaneous approach.
0WHD43Z	Insertion of infusion device into pericardial cavity, percutaneous endoscopic approach.
0WHD4YZ	Insertion of other device into pericardial cavity, percutaneous endoscopic approach.
0WPD00Z	Removal of drainage device from pericardial cavity, open approach.
0WPD01Z	Removal of radioactive element from pericardial cavity, open approach.
0WPD03Z	Removal of infusion device from pericardial cavity, open approach.
0WPD0YZ	Removal of other device from pericardial cavity, open approach.
0WPD30Z	Removal of drainage device from pericardial cavity, percutaneous approach.
0WPD31Z	Removal of radioactive element from pericardial cavity, percutaneous approach.
0WPD33Z	Removal of infusion device from pericardial cavity, percutaneous approach.
0WPD3YZ	Removal of other device from pericardial cavity, percutaneous approach.
0WPD40Z	Removal of drainage device from pericardial cavity, percutaneous endoscopic approach.
0WPD41Z	Removal of radioactive element from pericardial cavity, percutaneous endoscopic approach.
0WPD43Z	Removal of infusion device from pericardial cavity, percutaneous endoscopic approach.
0WPD4YZ	Removal of other device from pericardial cavity, percutaneous endoscopic approach.
0WWD00Z	Revision of drainage device in pericardial cavity, open approach.
0WWD01Z	Revision of radioactive element in pericardial cavity, open approach.
0WWD03Z	Revision of infusion device in pericardial cavity, open approach.
0WWD0YZ	Revision of other device in pericardial cavity, open approach.
0WWD30Z	Revision of drainage device in pericardial cavity, percutaneous approach.
0WWD31Z	Revision of radioactive element in pericardial cavity, percutaneous approach.
0WWD33Z	Revision of infusion device in pericardial cavity, percutaneous approach.
0WWD3YZ	Revision of other device in pericardial cavity, percutaneous approach.
0WWD40Z	Revision of drainage device in pericardial cavity, percutaneous endoscopic approach.
0WWD41Z	Revision of radioactive element in pericardial cavity, percutaneous endoscopic approach.
0WWD43Z	Revision of infusion device in pericardial cavity, percutaneous endoscopic approach.
0WWD4YZ	Revision of other device in pericardial cavity, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.24

ICD–10–PCS Code	Code description
02BN0ZX	Excision of pericardium, open approach, diagnostic.
02BN3ZX	Excision of pericardium, percutaneous approach, diagnostic.
02BN4ZX	Excision of pericardium, percutaneous endoscopic approach, diagnostic.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.31

ICD–10–PCS Code	Code description
025N0ZZ	Destruction of pericardium, open approach.
025N3ZZ	Destruction of pericardium, percutaneous approach.
025N4ZZ	Destruction of pericardium, percutaneous endoscopic approach.
02BN0ZZ	Excision of pericardium, open approach.
02BN3ZZ	Excision of pericardium, percutaneous approach.
02BN4ZZ	Excision of pericardium, percutaneous endoscopic approach.
02TN0ZZ	Resection of pericardium, open approach.
02TN3ZZ	Resection of pericardium, percutaneous approach.
02TN4ZZ	Resection of pericardium, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.61

ICD–10–PCS Code	Code description
5A02110	Assistance with cardiac output using balloon pump, intermittent.
5A02210	Assistance with cardiac output using balloon pump, continuous.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.67

ICD–10–PCS Code	Code description
02QA0ZZ	Repair heart, open approach.
02QA3ZZ	Repair heart, percutaneous approach.
02QA4ZZ	Repair heart, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.91

ICD–10–PCS Code	Code description
02QA0ZZ	Repair heart, open approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.99

ICD–10–PCS Code	Code description
02880ZZ	Division of conduction mechanism, open approach.
02883ZZ	Division of conduction mechanism, percutaneous approach.
02884ZZ	Division of conduction mechanism, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.05

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.05 are shown in Table 6P.1b for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.06

ICD–10–PCS Code	Code description
04C10ZZ	Extirpation of matter from celiac artery, open approach.
04C13ZZ	Extirpation of matter from celiac artery, percutaneous approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.06—Continued

ICD–10–PCS Code	Code description
04C14ZZ	Extirpation of matter from celiac artery, percutaneous endoscopic approach.
04C20ZZ	Extirpation of matter from gastric artery, open approach.
04C23ZZ	Extirpation of matter from gastric artery, percutaneous approach.
04C24ZZ	Extirpation of matter from gastric artery, percutaneous endoscopic approach.
04C30ZZ	Extirpation of matter from hepatic artery, open approach.
04C33ZZ	Extirpation of matter from hepatic artery, percutaneous approach.
04C34ZZ	Extirpation of matter from hepatic artery, percutaneous endoscopic approach.
04C40ZZ	Extirpation of matter from splenic artery, open approach.
04C43ZZ	Extirpation of matter from splenic artery, percutaneous approach.
04C44ZZ	Extirpation of matter from splenic artery, percutaneous endoscopic approach.
04C50ZZ	Extirpation of matter from superior mesenteric artery, open approach.
04C53ZZ	Extirpation of matter from superior mesenteric artery, percutaneous approach.
04C54ZZ	Extirpation of matter from superior mesenteric artery, percutaneous endoscopic approach.
04C60ZZ	Extirpation of matter from right colic artery, open approach.
04C63ZZ	Extirpation of matter from right colic artery, percutaneous approach.
04C64ZZ	Extirpation of matter from right colic artery, percutaneous endoscopic approach.
04C70ZZ	Extirpation of matter from left colic artery, open approach.
04C73ZZ	Extirpation of matter from left colic artery, percutaneous approach.
04C74ZZ	Extirpation of matter from left colic artery, percutaneous endoscopic approach.
04C80ZZ	Extirpation of matter from middle colic artery, open approach.
04C83ZZ	Extirpation of matter from middle colic artery, percutaneous approach.
04C84ZZ	Extirpation of matter from middle colic artery, percutaneous endoscopic approach.
04C90ZZ	Extirpation of matter from right renal artery, open approach.
04C93ZZ	Extirpation of matter from right renal artery, percutaneous approach.
04C94ZZ	Extirpation of matter from right renal artery, percutaneous endoscopic approach.
04CA0ZZ	Extirpation of matter from left renal artery, open approach.
04CA3ZZ	Extirpation of matter from left renal artery, percutaneous approach.
04CA4ZZ	Extirpation of matter from left renal artery, percutaneous endoscopic approach.
04CB0ZZ	Extirpation of matter from inferior mesenteric artery, open approach.
04CB3ZZ	Extirpation of matter from inferior mesenteric artery, percutaneous approach.
04CB4ZZ	Extirpation of matter from inferior mesenteric artery, percutaneous endoscopic approach.
04CC0ZZ	Extirpation of matter from right common iliac artery, open approach.
04CC3ZZ	Extirpation of matter from right common iliac artery, percutaneous approach.
04CC4ZZ	Extirpation of matter from right common iliac artery, percutaneous endoscopic approach.
04CD0ZZ	Extirpation of matter from left common iliac artery, open approach.
04CD3ZZ	Extirpation of matter from left common iliac artery, percutaneous approach.
04CD4ZZ	Extirpation of matter from left common iliac artery, percutaneous endoscopic approach.
04CE0ZZ	Extirpation of matter from right internal iliac artery, open approach.
04CE3ZZ	Extirpation of matter from right internal iliac artery, percutaneous approach.
04CE4ZZ	Extirpation of matter from right internal iliac artery, percutaneous endoscopic approach.
04CF0ZZ	Extirpation of matter from left internal iliac artery, open approach.
04CF3ZZ	Extirpation of matter from left internal iliac artery, percutaneous approach.
04CF4ZZ	Extirpation of matter from left internal iliac artery, percutaneous endoscopic approach.
04CH0ZZ	Extirpation of matter from right external iliac artery, open approach.
04CH3ZZ	Extirpation of matter from right external iliac artery, percutaneous approach.
04CH4ZZ	Extirpation of matter from right external iliac artery, percutaneous endoscopic approach.
04CJ0ZZ	Extirpation of matter from left external iliac artery, open approach.
04CJ3ZZ	Extirpation of matter from left external iliac artery, percutaneous approach.
04CJ4ZZ	Extirpation of matter from left external iliac artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.07

ICD–10–PCS Code	Code description
06C00ZZ	Extirpation of matter from inferior vena cava, open approach.
06C03ZZ	Extirpation of matter from inferior vena cava, percutaneous approach.
06C04ZZ	Extirpation of matter from inferior vena cava, percutaneous endoscopic approach.
06C10ZZ	Extirpation of matter from splenic vein, open approach.
06C13ZZ	Extirpation of matter from splenic vein, percutaneous approach.
06C14ZZ	Extirpation of matter from splenic vein, percutaneous endoscopic approach.
06C20ZZ	Extirpation of matter from gastric vein, open approach.
06C23ZZ	Extirpation of matter from gastric vein, percutaneous approach.
06C24ZZ	Extirpation of matter from gastric vein, percutaneous endoscopic approach.
06C40ZZ	Extirpation of matter from hepatic vein, open approach.
06C43ZZ	Extirpation of matter from hepatic vein, percutaneous approach.
06C44ZZ	Extirpation of matter from hepatic vein, percutaneous endoscopic approach.
06C50ZZ	Extirpation of matter from superior mesenteric vein, open approach.
06C53ZZ	Extirpation of matter from superior mesenteric vein, percutaneous approach.
06C54ZZ	Extirpation of matter from superior mesenteric vein, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.07—Continued

ICD–10–PCS Code	Code description
06C60ZZ	Extirpation of matter from inferior mesenteric vein, open approach.
06C63ZZ	Extirpation of matter from inferior mesenteric vein, percutaneous approach.
06C64ZZ	Extirpation of matter from inferior mesenteric vein, percutaneous endoscopic approach.
06C70ZZ	Extirpation of matter from colic vein, open approach.
06C73ZZ	Extirpation of matter from colic vein, percutaneous approach.
06C74ZZ	Extirpation of matter from colic vein, percutaneous endoscopic approach.
06C80ZZ	Extirpation of matter from portal vein, open approach.
06C83ZZ	Extirpation of matter from portal vein, percutaneous approach.
06C84ZZ	Extirpation of matter from portal vein, percutaneous endoscopic approach.
06C90ZZ	Extirpation of matter from right renal vein, open approach.
06C93ZZ	Extirpation of matter from right renal vein, percutaneous approach.
06C94ZZ	Extirpation of matter from right renal vein, percutaneous endoscopic approach.
06CB0ZZ	Extirpation of matter from left renal vein, open approach.
06CB3ZZ	Extirpation of matter from left renal vein, percutaneous approach.
06CB4ZZ	Extirpation of matter from left renal vein, percutaneous endoscopic approach.
06CC0ZZ	Extirpation of matter from right common iliac vein, open approach.
06CC3ZZ	Extirpation of matter from right common iliac vein, percutaneous approach.
06CC4ZZ	Extirpation of matter from right common iliac vein, percutaneous endoscopic approach.
06CD0ZZ	Extirpation of matter from left common iliac vein, open approach.
06CD3ZZ	Extirpation of matter from left common iliac vein, percutaneous approach.
06CD4ZZ	Extirpation of matter from left common iliac vein, percutaneous endoscopic approach.
06CF0ZZ	Extirpation of matter from right external iliac vein, open approach.
06CF3ZZ	Extirpation of matter from right external iliac vein, percutaneous approach.
06CF4ZZ	Extirpation of matter from right external iliac vein, percutaneous endoscopic approach.
06CG0ZZ	Extirpation of matter from left external iliac vein, open approach.
06CG3ZZ	Extirpation of matter from left external iliac vein, percutaneous approach.
06CG4ZZ	Extirpation of matter from left external iliac vein, percutaneous endoscopic approach.
06CH0ZZ	Extirpation of matter from right hypogastric vein, open approach.
06CH3ZZ	Extirpation of matter from right hypogastric vein, percutaneous approach.
06CH4ZZ	Extirpation of matter from right hypogastric vein, percutaneous endoscopic approach.
06CJ0ZZ	Extirpation of matter from left hypogastric vein, open approach.
06CJ3ZZ	Extirpation of matter from left hypogastric vein, percutaneous approach.
06CJ4ZZ	Extirpation of matter from left hypogastric vein, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.15

ICD–10–PCS Code	Code description
02CP0ZZ	Extirpation of matter from pulmonary trunk, open approach.
02CP3ZZ	Extirpation of matter from pulmonary trunk, percutaneous approach.
02CP4ZZ	Extirpation of matter from pulmonary trunk, percutaneous endoscopic approach.
02CQ0ZZ	Extirpation of matter from right pulmonary artery, open approach.
02CQ3ZZ	Extirpation of matter from right pulmonary artery, percutaneous approach.
02CQ4ZZ	Extirpation of matter from right pulmonary artery, percutaneous endoscopic approach.
02CR0ZZ	Extirpation of matter from left pulmonary artery, open approach.
02CR3ZZ	Extirpation of matter from left pulmonary artery, percutaneous approach.
02CR4ZZ	Extirpation of matter from left pulmonary artery, percutaneous endoscopic approach.
02CS0ZZ	Extirpation of matter from right pulmonary vein, open approach.
02CS3ZZ	Extirpation of matter from right pulmonary vein, percutaneous approach.
02CS4ZZ	Extirpation of matter from right pulmonary vein, percutaneous endoscopic approach.
02CT0ZZ	Extirpation of matter from left pulmonary vein, open approach.
02CT3ZZ	Extirpation of matter from left pulmonary vein, percutaneous approach.
02CT4ZZ	Extirpation of matter from left pulmonary vein, percutaneous endoscopic approach.
02CV0ZZ	Extirpation of matter from superior vena cava, open approach.
02CV3ZZ	Extirpation of matter from superior vena cava, percutaneous approach.
02CV4ZZ	Extirpation of matter from superior vena cava, percutaneous endoscopic approach.
03C00ZZ	Extirpation of matter from right internal mammary artery, open approach.
03C03ZZ	Extirpation of matter from right internal mammary artery, percutaneous approach.
03C04ZZ	Extirpation of matter from right internal mammary artery, percutaneous endoscopic approach.
03C10ZZ	Extirpation of matter from left internal mammary artery, open approach.
03C13ZZ	Extirpation of matter from left internal mammary artery, percutaneous approach.
03C14ZZ	Extirpation of matter from left internal mammary artery, percutaneous endoscopic approach.
03C20ZZ	Extirpation of matter from innominate artery, open approach.
03C23ZZ	Extirpation of matter from innominate artery, percutaneous approach.
03C24ZZ	Extirpation of matter from innominate artery, percutaneous endoscopic approach.
03C30ZZ	Extirpation of matter from right subclavian artery, open approach.
03C33ZZ	Extirpation of matter from right subclavian artery, percutaneous approach.
03C34ZZ	Extirpation of matter from right subclavian artery, percutaneous endoscopic approach.
03C40ZZ	Extirpation of matter from left subclavian artery, open approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.15—Continued

ICD–10–PCS Code	Code description
03C43ZZ	Extirpation of matter from left subclavian artery, percutaneous approach.
03C44ZZ	Extirpation of matter from left subclavian artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.16

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.16 are shown in Table 6P.1c for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.35

ICD–10–PCS Code	Code description
02BP0ZZ	Excision of pulmonary trunk, open approach.
02BP4ZZ	Excision of pulmonary trunk, percutaneous endoscopic approach.
02BQ0ZZ	Excision of right pulmonary artery, open approach.
02BQ4ZZ	Excision of right pulmonary artery, percutaneous endoscopic approach.
02BR0ZZ	Excision of left pulmonary artery, open approach.
02BR4ZZ	Excision of left pulmonary artery, percutaneous endoscopic approach.
02BS0ZZ	Excision of right pulmonary vein, open approach.
02BS4ZZ	Excision of right pulmonary vein, percutaneous endoscopic approach.
02BT0ZZ	Excision of left pulmonary vein, open approach.
02BT4ZZ	Excision of left pulmonary vein, percutaneous endoscopic approach.
02BV0ZZ	Excision of superior vena cava, open approach.
02BV4ZZ	Excision of superior vena cava, percutaneous endoscopic approach.
03B00ZZ	Excision of right internal mammary artery, open approach.
03B04ZZ	Excision of right internal mammary artery, percutaneous endoscopic approach.
03B10ZZ	Excision of left internal mammary artery, open approach.
03B14ZZ	Excision of left internal mammary artery, percutaneous endoscopic approach.
03B20ZZ	Excision of innominate artery, open approach.
03B24ZZ	Excision of innominate artery, percutaneous endoscopic approach.
03B30ZZ	Excision of right subclavian artery, open approach.
03B34ZZ	Excision of right subclavian artery, percutaneous endoscopic approach.
03B40ZZ	Excision of left subclavian artery, open approach.
03B44ZZ	Excision of left subclavian artery, percutaneous endoscopic approach.
05B00ZZ	Excision of azygos vein, open approach.
05B04ZZ	Excision of azygos vein, percutaneous endoscopic approach.
05B10ZZ	Excision of hemiazygos vein, open approach.
05B14ZZ	Excision of hemiazygos vein, percutaneous endoscopic approach.
05B30ZZ	Excision of right innominate vein, open approach.
05B34ZZ	Excision of right innominate vein, percutaneous endoscopic approach.
05B40ZZ	Excision of left innominate vein, open approach.
05B44ZZ	Excision of left innominate vein, percutaneous endoscopic approach.
05B50ZZ	Excision of right subclavian vein, open approach.
05B54ZZ	Excision of right subclavian vein, percutaneous endoscopic approach.
05B60ZZ	Excision of left subclavian vein, open approach.
05B64ZZ	Excision of left subclavian vein, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.36

ICD–10–PCS Code	Code description
04B10ZZ	Excision of celiac artery, open approach.
04B14ZZ	Excision of celiac artery, percutaneous endoscopic approach.
04B20ZZ	Excision of gastric artery, open approach.
04B24ZZ	Excision of gastric artery, percutaneous endoscopic approach.
04B30ZZ	Excision of hepatic artery, open approach.
04B34ZZ	Excision of hepatic artery, percutaneous endoscopic approach.
04B40ZZ	Excision of splenic artery, open approach.
04B44ZZ	Excision of splenic artery, percutaneous endoscopic approach.
04B50ZZ	Excision of superior mesenteric artery, open approach.
04B54ZZ	Excision of superior mesenteric artery, percutaneous endoscopic approach.
04B60ZZ	Excision of right colic artery, open approach.
04B64ZZ	Excision of right colic artery, percutaneous endoscopic approach.
04B70ZZ	Excision of left colic artery, open approach.
04B74ZZ	Excision of left colic artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.36—Continued

ICD–10–PCS Code	Code description
04B80ZZ	Excision of middle colic artery, open approach.
04B84ZZ	Excision of middle colic artery, percutaneous endoscopic approach.
04B90ZZ	Excision of right renal artery, open approach.
04B94ZZ	Excision of right renal artery, percutaneous endoscopic approach.
04BA0ZZ	Excision of left renal artery, open approach.
04BA4ZZ	Excision of left renal artery, percutaneous endoscopic approach.
04BB0ZZ	Excision of inferior mesenteric artery, open approach.
04BB4ZZ	Excision of inferior mesenteric artery, percutaneous endoscopic approach.
04BC0ZZ	Excision of right common iliac artery, open approach.
04BC4ZZ	Excision of right common iliac artery, percutaneous endoscopic approach.
04BD0ZZ	Excision of left common iliac artery, open approach.
04BD4ZZ	Excision of left common iliac artery, percutaneous endoscopic approach.
04BE0ZZ	Excision of right internal iliac artery, open approach.
04BE4ZZ	Excision of right internal iliac artery, percutaneous endoscopic approach.
04BF0ZZ	Excision of left internal iliac artery, open approach.
04BF4ZZ	Excision of left internal iliac artery, percutaneous endoscopic approach.
04BH0ZZ	Excision of right external iliac artery, open approach.
04BH4ZZ	Excision of right external iliac artery, percutaneous endoscopic approach.
04BJ0ZZ	Excision of left external iliac artery, open approach.
04BJ4ZZ	Excision of left external iliac artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.37

ICD–10–PCS Code	Code description
06B00ZZ	Excision of inferior vena cava, open approach.
06B04ZZ	Excision of inferior vena cava, percutaneous endoscopic approach.
06B10ZZ	Excision of splenic vein, open approach.
06B14ZZ	Excision of splenic vein, percutaneous endoscopic approach.
06B20ZZ	Excision of gastric vein, open approach.
06B24ZZ	Excision of gastric vein, percutaneous endoscopic approach.
06B40ZZ	Excision of hepatic vein, open approach.
06B44ZZ	Excision of hepatic vein, percutaneous endoscopic approach.
06B50ZZ	Excision of superior mesenteric vein, open approach.
06B54ZZ	Excision of superior mesenteric vein, percutaneous endoscopic approach.
06B60ZZ	Excision of inferior mesenteric vein, open approach.
06B64ZZ	Excision of inferior mesenteric vein, percutaneous endoscopic approach.
06B70ZZ	Excision of colic vein, open approach.
06B74ZZ	Excision of colic vein, percutaneous endoscopic approach.
06B80ZZ	Excision of portal vein, open approach.
06B84ZZ	Excision of portal vein, percutaneous endoscopic approach.
06B90ZZ	Excision of right renal vein, open approach.
06B94ZZ	Excision of right renal vein, percutaneous endoscopic approach.
06BB0ZZ	Excision of left renal vein, open approach.
06BB4ZZ	Excision of left renal vein, percutaneous endoscopic approach.
06BC0ZZ	Excision of right common iliac vein, open approach.
06BC4ZZ	Excision of right common iliac vein, percutaneous endoscopic approach.
06BD0ZZ	Excision of left common iliac vein, open approach.
06BD4ZZ	Excision of left common iliac vein, percutaneous endoscopic approach.
06BF0ZZ	Excision of right external iliac vein, open approach.
06BF4ZZ	Excision of right external iliac vein, percutaneous endoscopic approach.
06BG0ZZ	Excision of left external iliac vein, open approach.
06BG4ZZ	Excision of left external iliac vein, percutaneous endoscopic approach.
06BH0ZZ	Excision of right hypogastric vein, open approach.
06BH4ZZ	Excision of right hypogastric vein, percutaneous endoscopic approach.
06BJ0ZZ	Excision of left hypogastric vein, open approach.
06BJ4ZZ	Excision of left hypogastric vein, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.46

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.46 are shown in Table 6P.1d for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.47

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.47 are shown in Table 6P.1e for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

There is not an equivalent ICD–10–PCS code translation for ICD–9–CM procedure code 38.55.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.65

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.65 are shown in Table 6P.1f for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.66

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.66 are shown in Table 6P.1g for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.67

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.67 are shown in Table 6P.1h for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.85

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.85 are shown in Table 6P.1i for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.86

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.86 are shown in Table 6P.1j for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.87

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.87 are shown in Table 6P.1k for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.0

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.0 are shown in Table 6P.1l for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.1

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.1 are shown in Table 6P.1m for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.21

ICD–10–PCS Code	Code description
021V09P	Bypass superior vena cava to pulmonary trunk with autologous venous tissue, open approach.
021V09Q	Bypass superior vena cava to right pulmonary artery with autologous venous tissue, open approach.
021V09R	Bypass superior vena cava to left pulmonary artery with autologous venous tissue, open approach.
021V0AP	Bypass superior vena cava to pulmonary trunk with autologous arterial tissue, open approach.
021V0AQ	Bypass superior vena cava to right pulmonary artery with autologous arterial tissue, open approach.
021V0AR	Bypass superior vena cava to left pulmonary artery with autologous arterial tissue, open approach.
021V0JP	Bypass superior vena cava to pulmonary trunk with synthetic substitute, open approach.
021V0JQ	Bypass superior vena cava to right pulmonary artery with synthetic substitute, open approach.
021V0JR	Bypass superior vena cava to left pulmonary artery with synthetic substitute, open approach.
021V0KP	Bypass superior vena cava to pulmonary trunk with nonautologous tissue substitute, open approach.
021V0KQ	Bypass superior vena cava to right pulmonary artery with nonautologous tissue substitute, open approach.
021V0KR	Bypass superior vena cava to left pulmonary artery with nonautologous tissue substitute, open approach.
021V0ZP	Bypass superior vena cava to pulmonary trunk, open approach.
021V0ZQ	Bypass superior vena cava to right pulmonary artery, open approach.
021V0ZR	Bypass superior vena cava to left pulmonary artery, open approach.
021V49P	Bypass superior vena cava to pulmonary trunk with autologous venous tissue, percutaneous endoscopic approach.
021V49Q	Bypass superior vena cava to right pulmonary artery with autologous venous tissue, percutaneous endoscopic approach.
021V49R	Bypass superior vena cava to left pulmonary artery with autologous venous tissue, percutaneous endoscopic approach.
021V4AP	Bypass superior vena cava to pulmonary trunk with autologous arterial tissue, percutaneous endoscopic approach.
021V4AQ	Bypass superior vena cava to right pulmonary artery with autologous arterial tissue, percutaneous endoscopic approach.
021V4AR	Bypass superior vena cava to left pulmonary artery with autologous arterial tissue, percutaneous endoscopic approach.
021V4JP	Bypass superior vena cava to pulmonary trunk with synthetic substitute, percutaneous endoscopic approach.
021V4JQ	Bypass superior vena cava to right pulmonary artery with synthetic substitute, percutaneous endoscopic approach.
021V4JR	Bypass superior vena cava to left pulmonary artery with synthetic substitute, percutaneous endoscopic approach.
021V4KP	Bypass superior vena cava to pulmonary trunk with nonautologous tissue substitute, percutaneous endoscopic approach.
021V4KQ	Bypass superior vena cava to right pulmonary artery with nonautologous tissue substitute, percutaneous endoscopic approach.
021V4KR	Bypass superior vena cava to left pulmonary artery with nonautologous tissue substitute, percutaneous endoscopic approach.
021V4ZP	Bypass superior vena cava to pulmonary trunk, percutaneous endoscopic approach.
021V4ZQ	Bypass superior vena cava to right pulmonary artery, percutaneous endoscopic approach.
021V4ZR	Bypass superior vena cava to left pulmonary artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.22

ICD–10–PCS Code	Code description
021W09B	Bypass thoracic aorta to subclavian with autologous venous tissue, open approach).
021W09D	Bypass thoracic aorta to carotid with autologous venous tissue, open approach).
021W0AB	Bypass thoracic aorta to subclavian with autologous arterial tissue, open approach.
021W0AD	Bypass thoracic aorta to carotid with autologous arterial tissue, open approach.
021W0JB	Bypass thoracic aorta to subclavian with synthetic substitute, open approach.
021W0JD	Bypass thoracic aorta to carotid with synthetic substitute, open approach.
021W0KB	Bypass thoracic aorta to subclavian with nonautologous tissue substitute, open approach.
021W0KD	Bypass thoracic aorta to carotid with nonautologous tissue substitute, open approach.
021W0ZB	Bypass thoracic aorta to subclavian, open approach.
021W0ZD	Bypass thoracic aorta to carotid, open approach.
021W49B	Bypass thoracic aorta to subclavian with autologous venous tissue, percutaneous endoscopic approach.
021W49D	Bypass thoracic aorta to carotid with autologous venous tissue, percutaneous endoscopic approach.
021W4AB	Bypass thoracic aorta to subclavian with autologous arterial tissue, percutaneous endoscopic approach.
021W4AD	Bypass thoracic aorta to carotid with autologous arterial tissue, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.22—Continued

ICD–10–PCS Code	Code description
021W4JB	Bypass thoracic aorta to subclavian with synthetic substitute, percutaneous endoscopic approach.
021W4JD	Bypass thoracic aorta to carotid with synthetic substitute, percutaneous endoscopic approach.
021W4KB	Bypass thoracic aorta to subclavian with nonautologous tissue substitute, percutaneous endoscopic approach.
021W4KD	Bypass thoracic aorta to carotid with nonautologous tissue substitute, percutaneous endoscopic approach.
021W4ZB	Bypass thoracic aorta to subclavian, percutaneous endoscopic approach.
021W4ZD	Bypass thoracic aorta to carotid, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.23

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.23 are shown in Table 6P.1n for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.25

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.25 are shown in Table 6P.1o for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.26

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.26 are shown in Table 6P.1p for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.52

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.52 are shown in Table 6P.1q for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.54

ICD–10–PCS Code	Code description
02QW0ZZ	Repair thoracic aorta, open approach.
02QW3ZZ	Repair thoracic aorta, percutaneous approach.
02QW4ZZ	Repair thoracic aorta, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.72

ICD–10–PCS Code	Code description
03LR0DZ	Occlusion of face artery with intraluminal device, open approach.
03LR3DZ	Occlusion of face artery with intraluminal device, percutaneous approach.
03LR4DZ	Occlusion of face artery with intraluminal device, percutaneous endoscopic approach.
03LS0DZ	Occlusion of right temporal artery with intraluminal device, open approach.
03LS3DZ	Occlusion of right temporal artery with intraluminal device, percutaneous approach.
03LS4DZ	Occlusion of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03LT0DZ	Occlusion of left temporal artery with intraluminal device, open approach.
03LT3DZ	Occlusion of left temporal artery with intraluminal device, percutaneous approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.72—Continued

ICD–10–PCS Code	Code description
03LT4DZ	Occlusion of left temporal artery with intraluminal device, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.75

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.75 are shown in Table 6P.1r for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.76

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.76 are shown in Table 6P.1s for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.79

ICD–10–PCS Code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.79 are shown in Table 6P.1t for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

As previously stated, we separated the more complex, more invasive procedures from the less complex, less invasive procedures to continue our evaluation of the procedures assigned to MS–DRGs 237 and 238. Our data analysis showed that the distribution of cases, the average length of stay, and average costs of the more complex, more invasive aortic and heart assist procedures and the less complex, less invasive other cardiovascular procedures would be more appropriately reflected if we classified these distinguishing types of procedures under newly created MS–DRGs, as reflected in the table below.

MAJOR CARDIOVASCULAR PROCEDURES WITH AND WITHOUT MCC

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 237 and 238—Combined	50,567	5.8	$29,174
MS–DRGs 237 and 238—Cases with more complex, more invasive procedure codes (37.41; 37.49; 37.55; 37.64; 38.04; 38.14; 38.34; 38.44; 38.64; 38.84; 39.24; 39.71, and 39.78)	22,278	4.0	31,729
MS–DRGs 237 and 238—Cases with less complex, less invasive procedure codes (35.00; 35.01; 35.02; 35.03; 35.04; 37.12; 37.24; 37.31; 37.61; 37.67; 37.91; 37.99; 38.05; 38.06; 38.07; 38.15; 38.16; 38.35; 38.36; 38.37; 38.46; 38.47; 38.55; 38.65; 38.66; 38.67; 38.85; 38.86; 38.87; 39.0; 39.1; 39.21; 39.22; 39.23; 39.25; 39.26; 39.52; 39.54; 39.72; 39.75; 39.76; and 39.79)	28,289	7.1	27,162

Our clinical advisors reviewed the results of the analysis and agreed that distinguishing the more complex, more invasive procedures from the less complex, less invasive procedures would result in improved clinical coherence for the various cardiovascular procedures currently assigned to MS–DRGs 237 and 238, as listed previously. Therefore, for FY 2016, we proposed to delete MS–DRGs 237 and 238. When we applied our established criteria to determine if the creation of a new CC or MCC subgroup within a base MS–DRG is warranted, we determined that a 2-way severity level split (with MCC and without MCC) was justified. Therefore, we proposed to create two new MS–DRGs that would contain the more complex, more invasive aortic and heart assist procedures currently assigned to MS–DRGs 237 and 238, as listed previously. We proposed to create MS–DRG 268, entitled ''Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC,'' and MS–DRG 269, entitled ''Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.'' The table below shows the distribution of cases and the average length of stay and average costs of the more complex, more invasive procedures for aortic and heart assistance for the proposed new MS–DRGs 268 and 269.

PROPOSED NEW MS–DRGS FOR AORTIC AND HEART ASSIST PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
Proposed New MS–DRG 268 with MCC	4,182	10.03	$45,996
Proposed New MS–DRG 269 without MCC	18,096	2.68	28,431

We invited public comments on this proposal and the ICD–10–PCS code translations for these procedures shown earlier in this section, which we also proposed to assign to proposed new MS–DRGs 268 and 269.

In addition, when we further applied our established criteria to determine if the creation of a new CC or MCC subgroup for the remaining procedures was warranted, we determined that a 3-way severity level split (with MCC, with CC, and without CC/MCC) was justified. Therefore, we proposed to create three new MS–DRGs that would contain the remaining cardiovascular procedures that were designated as the less complex, less invasive procedures, as listed previously. For FY 2016, we proposed to create MS–DRG 270, entitled ''Other Major Cardiovascular Procedures with MCC''; MS–DRG 271, entitled ''Other Major Cardiovascular Procedures with CC''; and MS–DRG 272, entitled ''Other Major Cardiovascular Procedures without CC/MCC,'' and to assign the less complex, less invasive cardiovascular procedures shown earlier in this section to these proposed new MS–DRGs. We believed that, as shown in the table below, the distribution of cases and average length of stay and average costs of these procedures would be more appropriately reflected when these types of procedures are classified under these proposed new MS–DRGs.

PROPOSED NEW MS–DRGS FOR OTHER MAJOR CARDIOVASCULAR PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
Proposed New MS–DRG 270 with MCC	14,158	9.3	$33,507
Proposed New MS–DRG 271 with CC	9,648	5.99	22,800
Proposed New MS–DRG 272 without CC/MCC	4,483	3.08	16,438

We invited public comments on this proposal and the ICD–10–PCS code translations for the less complex, less invasive cardiovascular procedures shown earlier in this section, which we also proposed to assign to proposed new MS–DRGs 270, 271, and 272.

In summary, for FY 2016, we proposed to delete MS–DRGs 237 and 238, and to create the following five new MS–DRGs:

- Proposed new MS–DRG 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC);
- Proposed new MS–DRG 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC);
- Proposed new MS–DRG 270 (Other Major Cardiovascular Procedures with MCC);
- Proposed new MS–DRG 271 (Other Major Cardiovascular Procedures with CC); and
- Proposed new MS–DRG 272 (Other Major Cardiovascular Procedures without CC/MCC).

We also proposed to assign the more complex, more invasive cardiovascular procedures identified in our analysis and the ICD–10–PCS code translations to proposed new MS–DRGs 268 and 269. In addition, we proposed to assign the less complex, less invasive cardiovascular procedures identified in our analysis and the ICD–10–PCS code translations to proposed new MS–DRGs 270, 271, and 272. We encouraged public comments on our proposal to create these proposed new MS–DRGs, as well as the ICD–10–PCS code translations that we proposed to assign to the corresponding proposed new MS–DRGs.

Comment: Several commenters supported the proposal to delete MS–DRGs 237 and 238 and to create five new proposed MS–DRGs 268, 269, 270, 271, and 272 to distinguish the more complex, more invasive procedures from the less complex, less invasive procedures resulting in improved clinical coherence for the various cardiovascular procedures currently assigned to MS–DRGs 237 and 238. Commenters stated that the proposal was reasonable, given the data and information provided.

One commenter who supported the creation of proposed new MS–DRGs 268 and 269 expressed additional support with regard to how these proposed new MS–DRGs would incorporate selected high resource surgical aortic and visceral vessel procedures, as well as selected high resource extra-cardiac procedures. The commenter agreed that, in terms of resource utilization and clinical coherency, the procedures included would be classified appropriately to the proposed new MS–DRGs. However, this commenter requested clarification on some of the ICD–10–PCS code translations that were listed for ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta). The commenter stated that, as displayed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24363), the dilation of right and left renal arteries and the superior mesenteric artery (procedures described by ICD–10–PCS codes 04793DZ through 04754DZ) also appear to be proposed for grouping to proposed MS–DRGs 268 and 269. The commenter believed that CMS did not intend to classify those dilation codes as ''stand alone'' procedures that would be assigned to proposed new MS–DRGs 268 and 269. The commenter stated that the ICD–10–PCS dilation codes should not be necessary as translations for ICD–9–CM procedure code 39.78.

Another commenter commended CMS on the timing of the proposal to establish proposed new MS–DRGs 268 and 269. The commenter stated that this proposal will allow patients requiring fenestrated grafts continued access to care in FY 2016, as the new-technology add-on payment for the Zenith Fenestrated Graft device is expiring September 30, 2015. The commenter also stated that, currently, there is not an appropriate mechanism to ensure access to these procedures, especially in rural hospitals, and that this proposal would change that.

Other commenters stated that the proposed new MS–DRGs would better recognize clinical homogeneity and

resource requirements for the range of major cardiovascular procedures.

Response: We appreciate the commenters' support of our proposal to delete MS–DRGs 237 and 238 and to create proposed new MS–DRGs 268 through 272.

In response to the comment requesting clarification on some of the ICD–10–PCS code translations that were listed for ICD–9–CM procedure code 39.78, the commenter is correct. It was not our intent to classify those dilation codes (ICD–10–PCS codes 04793DZ through 04754DZ) as ''stand alone'' procedures that would be assigned to proposed new MS–DRGs 268 and 269. Rather, we proposed those codes for consideration as supplemental codes to more fully describe the procedure performed. We agree with the commenter that these dilation codes are not necessary translations for ICD–9–CM procedure code 39.78 and as ''stand alone'' procedures they would be assigned to their own separate and clinically appropriate ICD–10 MS–DRG.

As we reviewed the translations for ICD–9–CM procedure code 39.78 in response to the commenter's request, we reviewed all the comparable ICD–10–PCS code translations that we proposed to assign to proposed new MS–DRGs 268 through 272. Specifically, we reviewed the list of the more complex, more invasive procedures that we proposed to assign to proposed MS–DRGs 268 and 269 and the list of the less complex, less invasive procedures that we proposed to assign to proposed MS–DRGs 270 through 272. We determined that the ICD–10–PCS translations for ICD–9–CM procedure code 37.49 (Other repair of heart and pericardium) as displayed in Table 6P.1a of the proposed rule were not complete. There was an inadvertent omission of an additional 78 ICD–10–PCS comparable code translations. Therefore, we are providing an updated Table 6P for this final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We note that this list of ICD–10–PCS code translations for ICD–9–CM procedure code 37.49 is consistent with the list of possible code translations found in the General Equivalency Maps (GEMs) files provided for public use available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*.

In conducting this review, our clinical advisors also determined that ICD–9–CM procedure code 37.49 and the corresponding ICD–10–PCS comparable code translations would be more appropriately classified under proposed new MS–DRGs 270 through 272 versus proposed new MS–DRGs 268 and 269. This decision is consistent with our proposal to assign less invasive procedures, such as pericardiotomies and pulsation balloon implants, to proposed new MS–DRGs 270 through 272. This procedure code captures procedures that are similar to the other procedures included in the proposal for MS–DRGs 270 through 272 involving the pericardium such as ICD–9–CM procedure codes 37.12 (Pericardiotomy), 37.24 (Biopsy of pericardium) and 37.61 (Pericardiectomy) and does not relate to the more complex, more invasive aortic and heart assist procedures that we proposed to assign to proposed MS–DRGs 268 and 269. According to our clinical advisors, the ICD–10–PCS code translations for ICD–9–CM procedure code 37.49 also do not constitute the level of complexity or resources similar to the other procedures that we proposed to assign to proposed new MS–DRGs 268 and 269. In addition, our clinical advisors determined that ICD–9–CM procedure code 39.54 (Re-entry operation (aorta)) and the corresponding ICD–10–PCS comparable code translations would be more appropriately classified under proposed new MS–DRGs 268 through 269 versus proposed new MS–DRGs 270 through 272. This decision is consistent with our proposal to assign more invasive procedures, such as open and endovascular repairs of the aorta with replacement grafts, to proposed new MS–DRGs 268 and 269. According to our clinical advisors, the procedure described by ICD–9–CM procedure code 39.54 and the comparable ICD–10–PCS code translations are precisely indicated for the aorta, and, as such, the procedure code belongs under proposed new MS–DRGs 268 and 269 along with the other aorta and heart assist procedures.

Comment: One commenter requested clarification on certain ICD–10–PCS code translations for proposed new MS–DRGs 268 through 272 and how they relate to the General Equivalency Maps (GEMs) and ICD–10–PCS to ICD–9–CM Reimbursement Mappings files. The commenter noted that there were instances where more than one ICD–9–CM procedure code could be translated to an ICD–10–PCS code that was included in the proposed new MS–DRGs, as well as listed in the Reimbursement Mappings file. The commenter submitted an example where ICD–10–PCS code 04V00DZ (Restriction of abdominal aorta with intraluminal device, open approach) was listed as a comparable ICD–10–PCS translation for ICD–9–CM procedure code 39.52 (Other repair of aneurysm) in the proposal for proposed new MS–DRGs 270 through 272. However, the commenter stated that, in the FY 2015 Reimbursement Mappings file, this same ICD–10–PCS code (04V00DZ) was shown to map to ICD–9–CM procedure code 39.71 (Endovascular implantation of other graft in abdominal aorta), which was included in the proposal for proposed new MS–DRGs 268 and 269. The commenter asked if the FY 2016 Reimbursement Mappings file would be updated to reflect that ICD–10–PCS code 04V00DZ maps back to ICD–9–CM procedure code 39.52.

Response: We acknowledge and appreciate the commenter's request for clarification. We point out that the General Equivalence Mappings (GEMs) and Reimbursement Mappings files were developed as resources for the public and are updated separate from the IPPS rulemaking. The GEMs were developed to provide users with a code to code translation reference tool for both ICD–9–CM and ICD–10 codes sets and to offer acceptable translation alternatives where possible. The Reimbursement Mappings were created to provide a temporary mechanism for mapping records containing ICD–10 codes to ''MS–DRG reimbursement minimum impact'' ICD–9–CM codes and allow claims processing by legacy systems while systems were being converted to process ICD–10 claims directly. The GEMs have been updated on an annual basis as part of the ICD–10 Coordination and Maintenance Committee meetings process and will continue to be updated for approximately 3 years after ICD–10 is implemented. We refer readers to the ICD–10 Coordination and Maintenance Committee Meeting Materials for further information related to discussion of GEMs updates, which can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*. The Reimbursement Mappings have been updated on an annual basis in preparation for the transition to ICD–10 implementation. As stated on the CMS ICD–10 Coordination and Maintenance Committee Meeting Web page available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*, the FY 2016 Reimbursement Mappings files will be posted in August 2015.

Comment: One commenter who supported proposed new MS–DRGs 268 and 269 requested that CMS revise the

titles to address concerns expressed by stakeholders. According to the commenter, the proposed titles have caused confusion among providers and consultants. The commenter suggested that CMS consider the following three modifications:

- Indicate that MS–DRGs 268 and 269 are aortic procedures, not aortic heart assist devices;
- Indicate that MS–DRGs 268 and 269 are assigned to heart assist removal or repair, and not the multitude of other heart assist insertion procedures not addressed in the proposed rule; and
- Remove the reference to pulsation balloon insertion, or add the reference to proposed new MS–DRGs 270 through 272 (Other Major Cardiovascular Procedures with MCC, with CC and without CC/MCC, respectively).

The commenter noted that the titles for proposed new MS–DRGs 268 and 269 contain the phrase ''Heart Assist Procedures''. However, the commenter stated that not *all* heart assist procedures are proposed to be assigned to these MS–DRGs; essentially, it is only the removal of heart assist procedures codes that are included. The commenter further noted that other heart assist procedures such as insertion of heart assist devices are identified in several other MS–DRGs, such as MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System w MCC and without MCC, respectively) and that external heart assist devices are identified in MS–DRG 215 (Other Heart Assist System Implant), while heart assist devices inserted percutaneously with cardiac catheterization are identified in MS–DRGs 216 through 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC and without CC/MCC, respectively).

The commenter also stated that the reference to ''Except Pulsation Balloon'' in the titles for proposed new MS–DRGs 268 and 269 indicates that *all* aortic and heart assist procedures would be included *except* pulsation balloon. The commenter asserted that the titles could cause confusion for stakeholders because there are other procedures that are nonpulsation balloon, heart assist procedures that correspond to the titles for proposed new MS–DRGs 268 and 269 and are assigned to other MS–DRGs. The commenter requested that CMS delete the terminology of pulsation balloon completely or remove it from proposed new MS–DRGs 268 and 269 and add it to proposed new MS–DRGs 270 through 272. The commenter maintained that incorporating the reference to pulsation balloon into proposed new MS–DRGs 270 through 272 would afford a clearer understanding of the procedures that are assigned for providers.

The commenter provided suggestions for the revision to the titles that CMS should take into consideration for proposed new MS–DRGs 268 through 272 as follows:

- Suggested retitle of proposed new MS–DRG 268: ''Aortic Procedures and Heart Assist Removal or Repair with MCC'';
- Suggested retitle of proposed new MS–DRG 269: ''Aortic Procedures and Heart Assist Removal or Repair without MCC'';
- Suggested retitle of proposed new MS–DRG 270: ''Pulsation Balloon and Other Major Cardiovascular Procedures with MCC'';
- Suggested retitle of proposed new MS–DRG 271: ''Pulsation Balloon and Other Major Cardiovascular Procedures with CC''; and
- Suggested retitle of proposed new MS–DRG 272: ''Pulsation Balloon and Other Major Cardiovascular Procedures without CC/MCC''.

Response: We acknowledge the commenter's request to consider revisions to the titles for proposed new MS–DRGs 268 through 272. However, we note that we did not receive any other comments from stakeholders expressing confusion with regard to the titles for these proposed new MS–DRGs or the assignment of heart assist procedures.

The commenter is correct that not *all* heart assist procedures are being proposed for assignment to proposed new MS–DRGs 268 and 269. As the commenter pointed out, there are other heart assist procedures that group to various MS–DRGs. The proposal was based on ICD–9–CM procedure codes that are currently assigned to MS–DRGs 237 and 238 and the corresponding ICD–10–PCS code translations for proposed new MS–DRGs 268 through 272. We believe that stakeholders understand that the MS–DRG system is a classification scheme consisting of clinically similar groups of patients with similar resource intensity, and that while the titles of the MS–DRGs reflect the category of procedures which may or may not be assigned to a particular MS–DRG, they do not specifically identify the details of each applicable procedure code. We also believe that stakeholders do not rely solely on the MS–DRG titles to determine what procedures are assigned to a particular MS–DRG. Rather, they would consult the MS–DRG Definitions Manual. The MS–DRG Definitions Manual contains the complete documentation of the MS–DRG GROUPER logic and is available from 3M/HIS, which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49905 through 49906), the MS–DRG Definitions Manual, Version 32, which includes the FY 2015 MS–DRG changes is available on a CD for $225. This manual may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949–0303; or by obtaining an order form at the Web site at: *http://www/3MHIS.com*. In addition, as discussed in section II.G.1.a. of this final rule, in November 2014, CMS made available a Definitions Manual of the ICD–10 MS–DRGs Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. Accordingly, we do not believe that the reference to ''Heart Assist Procedures'' in the title for proposed new MS–DRGs 268 and 269 would create confusion.

For this same reason, we also do not believe that including the reference to ''*except* pulsation balloon'' in the titles for proposed new MS–DRGs 268 and 269, to accurately reflect that the pulsation balloon procedure is not assigned to those MS–DRGs, necessarily indicates that all other aortic and heart assist procedures are included. We would expect stakeholders to consult the MS–DRG Definitions Manual as described above to identify and determine whether a particular procedure is assigned to MS–DRG 268 or 269 or to another MS–DRG, rather than relying on the MS–DRGs title alone.

After consideration of the public comments received, we are adopting as final our proposal to delete ICD–9–CM MS–DRGs 237 and 238 and add the following five new MS–DRGs to ICD–10 MS–DRGs Version 33:

- MS–DRG 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC);
- MS–DRG 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC);
- MS–DRG 270 (Other Major Cardiovascular Procedures with MCC);
- MS–DRG 271 (Other Major Cardiovascular Procedures with CC); and
- MS–DRG 272 (Other Major Cardiovascular Procedures without CC/MCC)

We agree that these modifications will more appropriately reflect payment while recognizing differences in complexity, resources and severity of illness for the various cardiovascular

procedures. These finalized ICD–10 MS–DRGs will include the updated assignments discussed above related to the ICD–10–PCS code translations for ICD–9–CM codes 37.49 (Other repair of heart and pericardium) and 39.54 (Re-entry operation (aorta)). We also refer readers to the updated Table 6P for this final rule which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Lastly, we will consider if further modifications to the titles of these MS–DRGs are warranted in future rulemaking.

4. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Revision of Hip or Knee Replacements: Proposed Revision of ICD–10–PCS Version 32 Logic

We received two comments that the logic for ICD–10 MS–DRGs Version 32 does not work the same as it does for the ICD–9–CM based MS–DRGs Version 32 for procedures involving joint revisions. One of the commenters requested that CMS change the MS–DRG structure for procedures involving joint revisions within the ICD–10 MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively) so that cases that have a spacer removed prior to the insertion of a new joint prosthesis are assigned to MS–DRG 466, 467, and 468, as is the case with the ICD–9–CM MS–DRGs. The other commenter asked that joint revision cases that involve knee revisions with cemented and uncemented qualifiers be assigned to these MS–DRGs. This commenter provided an example of a patient admitted for a knee revision and reported under ICD–10–PCS codes 0SPD0JZ (Removal of synthetic substitute from left knee joint, open approach) and 0SRU0JA (Replacement of left knee joint, femoral surface with synthetic substitute, uncemented, open approach), which should be assigned to MS–DRGs 466, 467, and 468. The requestor stated that joint revision cases reported with ICD–9–CM codes are assigned to MS–DRGs 466, 467, and 468, but similar cases reported with the corresponding ICD–10–PCS codes are not assigned to MS–DRGs 466, 467, and 468 in ICD–10–PCS MS–DRGs Version 32.

We agree that joint revision cases involving the removal of a spacer and subsequent insertion of a new joint prosthesis should be assigned to ICD–10 MS–DRGs 466, 467, and 468 as is the case currently with the ICD–9–CM based MS–DRGs Version 32. We also agree that knee revision cases that involve cemented and uncemented qualifiers should be assigned to ICD–10 MS–DRGs 466, 467, and 468. Knee revision cases currently reported with ICD–9–CM codes are assigned to MS–DRGs 466, 467, and 468 in the ICD–9–CM based MS–DRGs. We examined joint revision combination codes that are not currently assigned to MS–DRGs 466, 467, and 468 in ICD–10 MS–DRGs Version 32 and identified additional combinations that also should be included so that the joint revision ICD–10 MS–DRGs would have the same logic as the ICD–9–CM MS–DRGs. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24379 through 24395), we proposed to add code combinations listed in a table in the proposed rule that would capture the joint revisions to the Version 33 MS–DRG structure for ICD–10 MS–DRGs 466, 467, and 468 that we proposed to implement effective October 1, 2015. We invited public comments on our proposal to add the joint revision code combinations to MS–DRGs 466, 467, and 468 that were listed in the table in the proposed rule (80 FR 24379 through 24395).

Comment: A number of commenters supported the proposal to add the joint revision code combinations to MS–DRGs 466, 467, and 468. The commenters stated that the proposal was reasonable, given the data and information provided. One commenter commended CMS for its careful review of these code pairs for hip and knee revision cases and supported the proposed updates. Another commenter supported the proposed MS–DRG assignment changes which the commenter believed would help to ensure that the ICD–10 MS–DRGs capture the appropriate ICD–10 procedure codes. One commenter stated that the proposed MS–DRG assignment changes improve alignment of these cases under the ICD–10 framework.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments we received, we are finalizing our proposal to add code combinations which capture the joint revision procedures set forth in the table below to the Version 33 MS–DRG structure for ICD–10 MS–DRGs 466, 467, and 468 that will be implemented effective October 1, 2015. We note that joint revision procedures are also included in the ICD–9–CM version of MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional, and Metabolic Operating Room Procedures with MCC, with CC, and without CC/MCC, respectively). Therefore, to ensure that the joint revision ICD–10 MS–DRGs would have the same logic as the ICD–9–CM MS–DRGs, any updates to the joint revision combinations would apply to MS–DRGs 466, 467, and 468 as well as MS–DRGs 628, 629, and 630 because both sets of MS–DRGs contain the same joint revision codes. These comparable joint revisions combinations updates also will be made to MS–DRGs 628, 629, and 630 in the Version 33 MS–DRG structure for ICD–10 to maintain consistency with the logic for the ICD–9–CM MS–DRGs, effective October 1, 2015. Therefore, the joint revision combination codes that we are finalizing in this final rule are the same for MS–DRGs 466, 467, 468, 628, 629, and 630 and are reflected in the updated table below.

MS–DRGs 466–468 and 628–630 ICD–10–PCS Code Pairs Added to the Version 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, and 630: New Hip Revision ICD–10–PCS Combinations

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA01A	Replacement of right hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, pen approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular surface with synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA01A	Replacement of right hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular surface with synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA01A	Replacement of right hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular surface with synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic substitute, uncemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SP90JZ	Removal of synthetic substitute from right hip joint, open approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP90JZ	Removal of synthetic substitute from right hip joint, open approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP90JZ	Removal of synthetic substitute from right hip joint, open approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA01A	Replacement of right hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular surface with synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA01A	Replacement of right hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular surface with synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach.
0SPB0JZ	Removal of synthetic substitute from left hip joint, open approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB0JZ	Removal of synthetic substitute from left hip joint, open approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB0JZ	Removal of synthetic substitute from left hip joint, open approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRC0J9	Replacement of right knee joint with synthetic substitute, cemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRC0JA	Replacement of right knee joint with synthetic substitute, uncemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRC0JZ	Replacement of right knee joint with synthetic substitute, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRT0J9	Replacement of right knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRT0JA	Replacement of right knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRT0JZ	Replacement of right knee joint, femoral surface with synthetic substitute, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRV0J9	Replacement of right knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRV0JA	Replacement of right knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach.
0SPC0JZ	Removal of synthetic substitute from right knee joint, open approach.	and	0SRT0J9	Replacement of right knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPC0JZ	Removal of synthetic substitute from right knee joint, open approach.	and	0SRT0JA	Replacement of right knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPC0JZ	Removal of synthetic substitute from right knee joint, open approach.	and	0SRV0J9	Replacement of right knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPC0JZ	Removal of synthetic substitute from right knee joint, open approach.	and	0SRV0JA	Replacement of right knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPC4JZ	Removal of synthetic substitute from right knee joint, percutaneous endoscopic approach.	and	0SRT0J9	Replacement of right knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPC4JZ	Removal of synthetic substitute from right knee joint, percutaneous endoscopic approach.	and	0SRT0JA	Replacement of right knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPC4JZ	Removal of synthetic substitute from right knee joint, percutaneous endoscopic approach.	and	0SRV0J9	Replacement of right knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPC4JZ	Removal of synthetic substitute from right knee joint, percutaneous endoscopic approach.	and	0SRV0JA	Replacement of right knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRD0J9	Replacement of left knee joint with synthetic substitute, cemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRD0JA	Replacement of left knee joint with synthetic substitute, uncemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRD0JZ	Replacement of left knee joint with synthetic substitute, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRU0J9	Replacement of left knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRU0JA	Replacement of left knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRU0JZ	Replacement of left knee joint, femoral surface with synthetic substitute, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRW0J9	Replacement of left knee joint, tibial surface with synthetic substitute, cemented, open approach.

MS–DRGs 466–468 AND 628–630 ICD–10–PCS CODE PAIRS ADDED TO THE VERSION 33 ICD–10 MS–DRGs 466, 467, 468, 628, 629, AND 630: NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRW0JA	Replacement of left knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach.
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRU0J9	Replacement of left knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRU0JA	Replacement of left knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRW0J9	Replacement of left knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRW0JA	Replacement of left knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRU0J9	Replacement of left knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRU0JA	Replacement of left knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRW0J9	Replacement of left knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRW0JA	Replacement of left knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach.

b. Spinal Fusion

We received a request to revise the titles of MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or 9+ Fusion with MCC, with CC, and without CC/MCC, respectively) for the ICD–10 MS–DRGs so that they more closely correspond to the terminology used to describe the ICD–10–PCS procedure codes without changing the ICD–10 MS–DRG logic. We agree with the requestor that revising the titles of these MS–DRGs would more appropriately identify the procedures classified under these groupings. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24395), we proposed new titles for these three MS–DRGs that would change the reference of ''9+ Fusions'' to ''Extensive Fusions.''

We invited public comments on our proposal.

Comment: Several commenters supported the proposal to modify the titles for ICD–10 MS–DRGs 456 through 458. The commenters stated that the proposal was reasonable, given the data and information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to modify the titles for ICD–10 MS–DRGs 456 through 458. The final title revisions to MS–DRGs 456, 457, and 458 for the FY 2016 ICD–10 MS–DRGs Version 33 are as follows:

- MS–DRG 456 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion with MCC);
- MS–DRG 457 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion with CC); and
- MS–DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion without CC/MCC).

5. MDC 14 (Pregnancy, Childbirth and the Puerperium): MS–DRG 775 (Vaginal Delivery Without Complicating Diagnosis)

We received a request to modify the logic for ICD–10 MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis) so that the procedure code for the induction of labor with a cervical ripening gel would not group to the incorrect MS–DRG when a normal delivery has occurred. ICD–10–PCS procedure code 3E0P7GC (Introduction of other therapeutic substance into female reproductive, via natural or artificial opening) describes this procedure.

We reviewed how this procedure code is currently classified under the ICD–10 MS–DRGs Version 32 and noted that it is currently designated as an operating room (O.R.) procedure code that affects MS–DRG assignment. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24395), we agreed with the requestor that the current logic for ICD–10–PCS procedure code 3E0P7GC did not result in the appropriate MS–DRG assignment. The result of our analysis suggested that this code should not be designated as an O.R. code. Our clinical advisors agreed that this procedure did not require the intensity or complexity of service and resource utilization to merit an O.R. designation under ICD–10. Therefore, in the proposed rule, we proposed to make ICD–10–PCS procedure code 3E0P7GC a non-O.R. code so that cases reporting this procedure code will group to the appropriate MS–DRG assignment. We invited public comments on our proposal.

Comment: Several commenters supported the proposal to modify the logic for ICD–10 MS–DRG 775 so that procedure code 3E0P7GC would not group to the incorrect MS–DRG when a normal delivery has occurred. The commenters stated that the proposal

was reasonable, given the data and information provided.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments received, we are finalizing our proposal to modify the logic for ICD–10 MS–DRG 775 so that ICD–10–PCS procedure code 3E0P7GC will not group to the incorrect MS–DRG when a normal delivery has occurred.

Our analysis of ICD–10–PCS procedure code 3E0P7GC also prompted the review of additional, similar codes that describe the introduction of a substance. We evaluated the following ICD–10–PCS procedure codes:

- 3E0P76Z (Introduction of nutritional substance into female reproductive, via natural or artificial opening);
- 3E0P77Z (Introduction of electrolytic and water balance substance into female reproductive, via natural or artificial opening);
- 3E0P7SF (Introduction of other gas into female reproductive, via natural or artificial opening);
- 3E0P83Z (Introduction of anti-inflammatory into female reproductive, via natural or artificial opening endoscopic);
- 3E0P86Z (Introduction of nutritional substance into female reproductive, via natural or artificial opening endoscopic);
- 3E0P87Z (Introduction of electrolytic and water balance substance into female reproductive, via natural or artificial opening endoscopic);
- 3E0P8GC (Introduction of other therapeutic substance into female reproductive, via natural or artificial opening endoscopic); and
- 3E0P8SF (Introduction of other gas into female reproductive, via natural or artificial opening endoscopic).

From our analysis, we determined that these codes also are currently designated as O.R. codes which affect MS–DRG assignment. Our clinical advisors recommended that these codes should also be designated as non-O.R. because they do not require the intensity or complexity of service and resource utilization to merit an O.R. designation under the ICD–10 MS–DRGs. As a result of our analysis and based on our clinical advisors' recommendation, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24395), we proposed to designate the above listed ICD–10–PCS procedure codes as non-O.R. procedure codes to ensure that these codes will group to the appropriate MS–DRG assignment.

We invited public comments on our proposal.

Comment: Several commenters agreed with the proposal to change the designation for the additional ICD–10–PCS codes listed in the proposed rule describing the introduction of a substance from O.R. to non-O.R. The commenters stated that the proposal was reasonable, given the data and information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to designate the following ICD–10–PCS procedure codes as non-O.R. for the FY 2016 ICD–10 MS–DRGs Version 33: 3E0P76Z; 3E0P77Z; 3E0P7SF; 3E0P83Z; 3E0P86Z; 3E0P87Z; 3E0P8GC; and 3E0P8SF.

6. MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): CroFab Antivenin Drug

We received a request that CMS change the MS–DRG assignment for antivenom cases from MS–DRG 917 and 918 (Poisoning & Toxic Effects of Drugs with and without MCC, respectively). For the FY 2016 IPPS/LTCH PPS proposed rule, for these MS–DRGs, we examined claims data from the December 2014 update of the FY 2014 MedPAR file for cases reporting ICD–9–CM diagnosis codes of a principal diagnosis 989.5 (Toxic effect of venom), a secondary diagnosis ICD–9–CM E code of E905.0 (Venomous snakes and lizards), and the ICD–9–CM procedure code of 99.16 (Injection of antidote), which is a non-O.R. code and does not impact the MS–DRG assignment.

For the ICD–9–CM diagnosis code 989.5 (Toxic effect of venom), the ICD–10–CM provides more detailed diagnosis codes for these toxic effects of venom cases as shown in the following table:

ICD–10–CM Code Translations for ICD–9–CM Diagnosis Code 989.5

ICD–10–CM Code	Code description
T63.001A	Toxic effect of unspecified snake venom, accidental (unintentional), initial encounter.
T63.011A	Toxic effect of rattlesnake venom, accidental (unintentional) initial encounter.
T63.021A	Toxic effect of coral snake venom, accidental (unintentional), initial encounter.
T63.031A	Toxic effect of taipan venom, accidental (unintentional), initial encounter.
T63.041A	Toxic effect of cobra venom, accidental (unintentional), initial encounter.
T63.061A	Toxic effect of venom of other North and South American snake, accidental (unintentional), initial encounter.
T63.71A	Toxic effect of venom of other Australian snake, accidental (unintentional), initial encounter.
T63.081A	Toxic effect of venom of other African and Asian snake, accidental (unintentional), initial encounter.
T63.091A	Toxic effect of venom of other snake, accidental (unintentional), initial encounter.

For the ICD–9–CM Supplementary Classification of External Causes of Injury and Poisoning code E905.0 (Venomous snakes and lizards), ICD–10–CM provides more detailed diagnosis codes for these cases as shown in the following table:

ICD–10–CM Code Translations for ICD–9–CM Code E905.0

ICD–10–CM Code	Code description
T63.001A	Toxic effect of unspecified snake venom, accidental (unintentional), initial encounter.
T63.011A	Toxic effect of rattlesnake venom, accidental (unintentional) initial encounter.
T63.021A	Toxic effect of coral snake venom, accidental (unintentional), initial encounter.
T63.031A	Toxic effect of taipan venom, accidental (unintentional), initial encounter.
T63.041A	Toxic effect of cobra venom, accidental (unintentional), initial encounter.
T63.061A	Toxic effect of venom of other North and South American snake, accidental (unintentional), initial encounter.

ICD–10–CM CODE TRANSLATIONS FOR ICD–9–CM CODE E905.0—Continued

ICD–10–CM Code	Code description
T63.71A	Toxic effect of venom of other Australian snake, accidental (unintentional), initial encounter.
T63.081A	Toxic effect of venom of other African and Asian snake, accidental (unintentional), initial encounter.
T63.091A	Toxic effect of venom of other snake, accidental (unintentional), initial encounter.

We examined claims data for reported cases involving injections for snake bites in MS–DRGs 917 and 918 from the December 2014 update of the FY 2014 MedPAR file. Our findings are displayed in the table below.

SNAKE BITE WITH INJECTIONS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 917—All cases	26,393	4.77	$9,983
MS–DRG 917—Cases with principal diagnosis code 989.5 and secondary diagnosis code E905.0 with procedure code 99.16 (non-OR)	0	0	0
MS–DRG 918—All cases	24,557	2.90	4,953
MS–DRG 918—Cases with principal diagnosis code 989.5 and secondary diagnosis code E905.0 with procedure code 99.16 (non-OR)	19	2.16	12,014

As shown in the table above, we identified 19 cases involving injections for snake bites reported in MS–DRG 918 only. In the FY 2016 IPPS/LTCH PPS proposed rule, we pointed out that this small number of cases (19) does not provide justification to create a new MS–DRG. The cases are assigned to the same MS–DRG as are other types of poisonings and toxic effects. We were unable to identify another MS–DRG that would be a more appropriate MS–DRG assignment for these cases based on the clinical nature of this condition. The MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. Basing a new MS–DRG on such a small number of cases (19) 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.

Our clinical advisors reviewed the data, evaluated these conditions, and recommended that we not change the MS–DRG assignment for procedures involving the injection of the CroFab antivenom drug for snake bites because these cases are clinically similar to other poisoning cases currently assigned to MS–DRGs 917 and 918. Based on the findings in our data analysis and the recommendations of our clinical advisors, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24397), we did not propose to create a new MS–DRG for cases of CroFab antivenom drugs for snake bites. We proposed to maintain the current assignment of diagnosis codes in MS–DRGs 917 and 918. We invited public comments on our proposal.

Comment: A number of commenters supported the proposal to maintain the current MS–DRG assignment for procedures involving CroFab antivenom. The commenters stated that the proposal was reasonable, given the data and information provided.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current MS–DRG assignment for procedures involving the CroFab antivenom drug for snakebites to MS–DRGs 917 and 918.

7. MDC 22 (Burns): Additional Severity of Illness Level for MS–DRG 927 (Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours With Skin Graft)

We received a request to add an additional severity level to MS–DRG 927 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation 96+ Hours with Skin Graft). The requestor was concerned about payment for severe burn cases that used dermal regenerative grafts. These grafts are captured by ICD–9–CM procedure code 86.67 (Dermal regenerative graft). The requestor stated that the total cost of these graft cases is significantly greater than the average total costs for all cases in MS–DRG 927. The requestor stated that the dermal regenerative grafts are used to cover large burns where donor skin is not available. The requestor stated that the grafts provide permanent covering of the wound and thus immediate closure of the wound. The requestor asserted that the grafts offer benefits such as the avoidance of infections. The requestor pointed out that MS–DRG 927 is not subdivided into severity of illness levels and recommended an additional severity level be added to address any payment issues for dermal regenerative grafts within MS–DRG 927.

ICD–10–PCS provides more detailed and specific codes for skin grafts. The ICD–10–PCS codes for skin grafts provide specific information on the part of the body receiving the skin graft, the type of graft, and the approach used to apply the graft. These codes can be found in the table labeled ''OHR (Replacement of Skin)'' in the ICD–10 MS–DRG Version 32 Definitions Manual available on the Internet at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.* As stated earlier, for the ICD–9–CM codes that result in greater than 50 ICD–10–PCS comparable code translations, we referred readers to Table 6P (ICD–10–PCS Code Translations for Final MS–DRG Changes), which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* The table includes the MDC topic, the ICD–9–CM code, and the ICD–10–PCS code translations. In Table 6P.2a, we show the comparable ICD–10–PCS codes for ICD–9–CM code 86.67 (Dermal regenerative graft).

We examined claims data for cases reported in MS–DRG 927 from the December 2014 update of the FY 2014

MedPAR file. The following table shows our findings.

EXTENSIVE BURNS OR FULL THICKNESS BURNS WITH MECHANICAL VENTILATION 96+ HOURS WITH SKIN GRAFT)

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 927—All cases	171	29.92	$113,844
MS–DRG 927—Cases with procedure code 86.67	22	33.5	146,903
MS–DRG 927—Cases with procedure code 86.67 and 96.72 (Mechanical ventilation for 96+ hours)	14	38.6	174,372
MS–DRG 927—Cases with procedure code 86.67 and without 96.72 (Mechanical ventilation for 96+ hours)	8	24.6	98,482
MS–DRG 927—All cases with MCC	131	31.51	121,519
MS–DRG 927—All cases with CC	38	25.21	91,910
MS–DRG 927—All cases without CC/MCC	2	15.00	27,872

As shown in the table above, we found a total of 171 cases in MS–DRG 927. Of these 171 cases, there were 131 cases with an MCC, 38 cases with a CC, and 2 cases without a CC or an MCC. We determined that the requested new severity level did not meet all of the criteria established in the FY 2008 IPPS final rule (72 FR 47169), and described in section II.G.1.b. of the preamble of the proposed rule, that must be met to warrant the creation of a CC or an MCC subgroup within a base MS–DRG. Specifically, the requested new severity level did not meet the criterion that there are at least 500 cases in the CC or MCC subgroup.

We also pointed out that the long-term mechanical ventilation cases are driving the costs to a greater extent than the graft cases. We found that the 22 cases that received a graft had average costs of $146,903. The 14 cases that had both 96+ hours of mechanical ventilation and a graft had average costs of $174,372. The 8 cases that had a graft but did not receive 96+ hours of mechanical ventilation had average costs of $98,482.

Our clinical advisors reviewed this issue and recommended making no MS–DRG updates for MS–DRG 927. They advised us that the dermal regenerative graft cases are appropriately assigned to the MS–DRG 927 because they are clinically similar to other cases within MS–DRG 927. Our clinical advisors also agreed that the cases in MS–DRG 927 do not meet the established criterion for creating a new severity level.

Based on the findings of our data analysis, the fact that MS–DRG 927 did not meet the criterion for the creation of an additional severity level, and the recommendations of our clinical advisors, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24397), we did not propose to create a new severity level for MS–DRG 927. We proposed to maintain the current MS–DRG 927 structure without additional severity levels. We invited public comments on our proposal.

Comment: A number of commenters supported the proposal to maintain the current MS–DRG 927 structure without creating additional severity levels. The commenters stated that the proposal was reasonable, given the data and information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current MS–DRG 927 structure without creating additional severity levels.

8. Medicare Code Editor (MCE) Changes

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 section II.G.1.a. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule and this final rule, CMS prepared the ICD–10 MS–DRGs Version 32 based on the FY 2015 MS–DRGs (Version 32) that we finalized in the FY 2015 IPPS/LTCH PPS final rule. In November 2014, we made available a Definitions Manual of the ICD–10 MS–DRGs Version 32 and the MCE Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.* We also prepared a document that described the changes made between Version 31–R to Version 32 to help facilitate a review of the ICD–10 MS–DRGs logic. We produced mainframe and computer software for ICD–10 MS–DRGs Version 32 and MCE Version 32, which was made available to the public in January 2015. Information on ordering the mainframe and computer software through NTIS was made available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRG GROUPER and MCE did not accurately reflect the logic and edits found in the ICD–9–CM MS–DRG GROUPER and the MCE.

For FY 2016, in order to be consistent with the ICD–9–CM MS–DRG GROUPER and MCE Version 32, we proposed to add the ICD–10–CM codes listed in the table below to the ICD–10 MCE Version 33 of the ''Manifestation codes not allowed as principal diagnosis'' edit. Under the MCE, manifestation codes describe the ''manifestation'' of an underlying disease, not the disease itself. Because these codes do not describe the disease itself, they should not be used as principal diagnoses.

ICD–10–CM CODES PROPOSED TO BE ADDED TO THE VERSION 33 MCE ''MANIFESTATION CODES NOT ALLOWED AS PRINCIPAL DIAGNOSIS'' EDIT

ICD–10–CM Code	Code description
D75.81	Myelofibrosis.
E08.00	Diabetes mellitus due to underlying condition with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC).
E08.01	Diabetes mellitus due to underlying condition with hyperosmolarity with coma.
E08.10	Diabetes mellitus due to underlying condition with ketoacidosis without coma.
E08.11	Diabetes mellitus due to underlying condition with ketoacidosis with coma.
E08.21	Diabetes mellitus due to underlying condition with diabetic nephropathy.
E08.22	Diabetes mellitus due to underlying condition with diabetic chronic kidney disease.
E08.29	Diabetes mellitus due to underlying condition with other diabetic kidney complication.
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema.
E08.319	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema.
E08.321	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema.
E08.329	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema.
E08.331	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema.
E08.339	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema.
E08.341	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema.
E08.349	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema.
E08.351	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema.
E08.359	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema.
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract.
E08.39	Diabetes mellitus due to underlying condition with other diabetic ophthalmic complication.
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified.
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy.
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy.
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy.
E08.44	Diabetes mellitus due to underlying condition with diabetic amyotrophy.
E08.49	Diabetes mellitus due to underlying condition with other diabetic neurological complication.
E08.51	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy without gangrene.
E08.52	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy with gangrene.
E08.59	Diabetes mellitus due to underlying condition with other circulatory complications.
E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy.
E08.618	Diabetes mellitus due to underlying condition with other diabetic arthropathy.
E08.620	Diabetes mellitus due to underlying condition with diabetic dermatitis.
E08.621	Diabetes mellitus due to underlying condition with foot ulcer.
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer.
E08.628	Diabetes mellitus due to underlying condition with other skin complications.
E08.630	Diabetes mellitus due to underlying condition with periodontal disease.
E08.638	Diabetes mellitus due to underlying condition with other oral complications.
E08.641	Diabetes mellitus due to underlying condition with hypoglycemia with coma.
E08.649	Diabetes mellitus due to underlying condition with hypoglycemia without coma.
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia.
E08.69	Diabetes mellitus due to underlying condition with other specified complication.
E08.8	Diabetes mellitus due to underlying condition with unspecified complications.
E08.9	Diabetes mellitus due to underlying condition without complications.

We invited public comment on our proposal to add the above list of ICD–10–CM diagnosis codes to the ''Manifestation codes not allowed as principal diagnosis'' edit in the FY 2016 ICD–10 MCE Version 33.

Comment: Several commenters supported the proposal to add the above listed ICD–10–CM diagnosis codes to the ''Manifestation codes not allowed as principal diagnosis'' edit in the FY 2016 ICD–10 MCE Version 33. The commenters stated that the proposed changes for the ICD–10 MCE seemed reasonable, given the data and information provided. However, one commenter asserted that the code description for ICD–10–CM diagnosis code D75.81, ''Myelofibrosis'', as displayed in the table in the proposed rule was inaccurate and that the more accurate long description is ''Secondary myelofibrosis''. The commenter stated that if the proposal for myelofibrosis under the ''Manifestation codes not allowed as principal diagnosis'' edit is restricted to ''secondary myelofibrosis,'' it would support the proposal. This commenter indicated that the disease of myelofibrosis is often the main reason for admission as it is a well-defined myeloproliferative neoplasm.

The commenter also noted it recently participated in proposals related to expanding coverage indications for hematopoietic stem cell transplant to include patients with a principal diagnosis of myelofibrosis. The commenter stated that primary or idiopathic myelofibrosis is coded with ICD–9–CM code 238.76 (Myelofibrosis with myeloid metaplasia) and will be reported with ICD–10–PCS code D47.1 (Chronic myeloproliferative disease). The commenter expressed a desire for coding of this condition to not create confusion as implementation of ICD–10 approaches and pledged to work with its members to confirm understanding.

Response: We appreciate the commenters' support of our proposal to add the listed ICD–10–CM diagnosis codes to the ICD–10 MCE Version 33 of the ''Manifestation codes not allowed as principal diagnosis'' edit. With regard to the commenter who asserted that the code description for ICD–10–CM diagnosis code D75.81 was inaccurate and that the more accurate long description is ''Secondary

myelofibrosis'', we point out that the official ICD–10–CM diagnosis code title description, as displayed in the 2015 Code Descriptions in Tabular Order file, which is available on the CMS ICD–10 Web site at *http://www.cms.gov/Medicare/Coding/ICD10/2015-ICD-10-CM-and-GEMs.html* in the Downloads section, is as presented in the FY 2016 IPPS/LTCH PPS proposed rule, ''Myelofibrosis''. In response to the commenter's statement that if the proposal for myelofibrosis under the ''Manifestation codes not allowed as principal diagnosis'' edit is restricted to ''secondary myelofibrosis,'' the commenter would support it, we note that ICD–10–CM diagnosis code D75.81 (Myelofibrosis) has an inclusion term of ''Secondary myelofibrosis NOS''. (Within ICD–10–CM, an inclusion term is defined as a term that is included under certain codes. The term represents a condition for which that code is to be used. The term may also be a synonym of the code title. We refer the reader to the ICD–10–CM Official Guidelines for Coding and Reporting for additional information related to inclusion terms.) As such, we believe the proposal to include ICD–10–CM diagnosis code D75.81 (Myelofibrosis) on the list of ''Manifestation codes not allowed as principal diagnosis'' edit is not inconsistent with the commenter's statement of support for a proposal restricted to ''secondary myelofibrosis.'' In response to the commenter indicating that the disease of myelofibrosis is often the main reason for admission as it is a well-defined myeloproliferative neoplasm, we note that, under both ICD–9–CM and ICD–10–CM, myelofibrosis is a manifestation code. As discussed previously, manifestation codes describe the manifestation of an underlying disease, not the disease itself, and therefore should not be used as a principal diagnosis. We also point out that a ''code first'' note appears at ICD–10–CM diagnosis code D75.81 (Myelofibrosis). The ''code first'' note is an etiology/manifestation coding convention (additional detail can be found in the ICD–10–CM Official Guidelines for Coding and Reporting), indicating that the condition has both an underlying etiology and manifestation due to the underlying etiology.

The commenter is correct that primary or idiopathic myelofibrosis is coded with ICD–9–CM code 238.76 (Myelofibrosis with myeloid metaplasia) and the comparable ICD–10–PCS procedure code translation is D47.1 (Chronic myeloproliferative disease). We also acknowledge and appreciate that the commenter stated its intent to work with its members to confirm understanding of coding as it relates to myelofibrosis as the transition to ICD–10 approaches. We encourage the commenter to review the ICD–10–CM Official Guidelines for Coding and Reporting to assist in that effort.

After consideration of the public comments we received, for FY 2016, we are finalizing our proposal to add the ICD–10–PCS codes listed earlier in this section to the ICD–10 MCE Version 33 ''Manifestation codes not allowed as principal diagnosis'' edit, which will ensure consistency with the ICD–9–CM MS–DRG GROUPER and MCE Version 32.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24398 through 24399), we also proposed to revise the language describing the ''Procedure inconsistent with LOS (Length of stay)'' edit which lists ICD–10–PCS code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours), effective for the FY 2016 ICD–10 MCE Version 33. Currently, in Version 32 of the ICD–10 MCE, the language describing this ''Procedure inconsistent with LOS (Length of stay)'' edit states: ''The following procedure should only be coded on claims with a length of stay of four days or greater.'' Because the code description of the ICD–10–PCS code is for ventilation that occurs *greater than* 96 consecutive hours, we proposed to revise the language for the edit to read: ''The following procedure code should only be coded on claims with a length of stay greater than 4 days.'' This proposed revision would clarify the intent of this MCE edit. We invited public comments on our proposal.

Comment: Several commenters supported the proposal to revise the language describing the ''Procedure inconsistent with LOS (Length of stay)'' edit. The commenters stated that the proposed changes seem reasonable, given the data and information provided.

Response: We appreciate the commenters' support.

Consistent with the proposal to revise the language for the ''Procedure inconsistent with LOS (Length of stay)'' edit because the code description for ICD–10–PCS code 5A1955Z is for ventilation that occurs *greater than* 96 consecutive hours, we determined that it is also necessary to revise the language for the corresponding ICD–10 MS–DRG titles that currently reference the ICD–9–CM terminology for mechanical ventilation of ''96 + hours'' based on the ICD–9–CM procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more) to instead reflect the terminology for the ICD–10–PCS code translation. Consistent with the logic for the ICD–9–CM MS–DRGs Version 32, ICD–10–PCS code 5A1955Z is assigned to these same MS–DRGs under the ICD–10 MS–DRGs Version 33. Under ICD–9–CM, the following six MS–DRGs contain GROUPER and MCE logic based on procedure code 96.72:

- MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except, Face Mouth and Neck with Major Operating Room Procedure);
- MS–DRG 004 (Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except, Face Mouth and Neck without Major Operating Room Procedure);
- MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+Hours);
- MS–DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation 96+ Hours);
- MS–DRG 927 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation 96+ Hours with Skin Graft); and
- MS–DRG 933 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation 96+ Hours without Skin Graft).

The following two MS–DRGs do not include GROUPER and MCE logic based on procedure code 96.72. However, the titles currently include the terminology for without mechanical ventilation of ''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 with CC).

Therefore, we are revising the titles for the corresponding ICD–10 MS–DRGs as the GROUPER and MCE logic include ICD–10–PCS code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours) or the language in the title of the MS–DRG includes without mechanical ventilation of ''96 + hours''. The revision to the titles is to add a ''greater than'' sign (>) before the 96 to reflect ''> 96 consecutive hours'' and to remove the ''plus sign'' (+) after the 96.

After consideration of the public comments received, we are finalizing our proposal to revise the language describing the ''Procedure inconsistent with LOS (Length of stay)'' edit which lists ICD–10–PCS code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours). Consistent with that proposal, we also are revising the ICD–

10 MS–DRG Version 33 titles as follows, effective for FY 2016.

- MS–DRG 003: ''(ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except, Face Mouth and Neck with Major Operating Room Procedure'';
- MS–DRG 004: ''Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except, Face Mouth and Neck without Major Operating Room Procedure'';
- MS–DRG 007: ''Respiratory System Diagnosis with Ventilator Support >96 Hours'';
- MS–DRG 870: ''Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours'';
- MS–DRG 871: ''Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with MCC'';
- MS–DRG 872: ''Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with CC'';
- MS–DRG 927: ''Extensive Burns or Full Thickness Burns with Mechanical Ventilation >96 Hours with Skin Graft''; and
- MS–DRG 933: ''Extensive Burns or Full Thickness Burns with Mechanical Ventilation >96 Hours without Skin Graft''.

9. 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.

Because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, for FY 2016, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

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 below.

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 proposed to make for FY 2016, as discussed in section II.G.3.e. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule, we proposed to revise the surgical hierarchy for MDC 5 (Diseases and Disorders of the Circulatory System) (80 FR 24399). Specifically, we proposed to delete MS–DRG 237 (Major Cardiovascular Procedures with MCC) and MS–DRG 238 (Major Cardiovascular Procedures without MCC) from the surgical hierarchy. We proposed to sequence proposed new MS–DRG 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC) and proposed new MS–DRG 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC) above proposed new MS–DRG 270 (Other Major Cardiovascular Procedures with MCC), proposed new MS–DRG 271 (Other Major Cardiovascular Procedures with CC), and proposed new MS–DRG 272 (Other Major Cardiovascular Procedures without CC/MCC). We proposed to sequence proposed new MS–DRGs 270, 271, and 272 above MS–DRG 239 (Amputation for Circulatory System Disorders Except Upper Limb & Toe with MCC). In addition, we proposed to sequence proposed new MS–DRG 273 (Percutaneous Intracardiac Procedures with MCC) and proposed new MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC) above MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-eluting Stent with MCC or 4+ Vessels/Stents).

We invited public comments on our proposals.

We did not receive any public comments on our proposals for the surgical hierarchy within MDC 5. Therefore, we are finalizing our proposals to delete ICD–9–CM MS–DRG 237 and ICD–9–CM MS–DRG 238 from the surgical hierarchy. We are adopting as final the sequencing of new ICD–10 MS–DRG 268 and new ICD–10 MS–DRG 269 above new ICD–10 MS–DRG 270, new ICD–10MS–DRG 271, and new ICD–10 MS–DRG 272. We also are finalizing our proposal to sequence new ICD–10 MS–DRGs 270, 271, and 272 above ICD–10 MS–DRG 239. Lastly, we are finalizing the sequencing of new ICD–10 MS–DRG 273 and new ICD–10 MS–DRG 274 above ICD–10 MS–DRG 246.

10. Changes to the MS–DRG Diagnosis Codes for FY 2016

a. Major Complications or Comorbidities (MCCs) and Complications or Comorbidities (CC) Severity Levels for FY 2016

A complete updated MCC, CC, and Non-CC Exclusion List is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as follows:

- Table 6I (Complete MCC list);
- Table 6J (Complete CC list); and
- Table 6K (Complete list of CC Exclusions).

b. Coronary Atherosclerosis Due to Calcified Coronary Lesion

We received a request that we change the severity levels for ICD–9–CM diagnosis codes 414.2 (Chronic total occlusion of coronary artery) and 414.4 (Coronary atherosclerosis due to calcified coronary lesion) from non-CCs to MCCs. The ICD–10–CM codes for these diagnoses are I25.82 (Chronic total occlusion of coronary artery) and I25.84 (Coronary atherosclerosis due to calcified coronary lesion), respectively, and both of these codes are currently classified as non-CCs.

This issue was previously discussed in the FY 2014 IPPS/LTCH PPS proposed rule and final rule (78 FR 27522 and 78 FR 50541 through 50542, respectively), and the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28018 and 28019 and 79 FR 49903 and 49904, respectively).

We examined claims data from the December 2014 update of the FY 2014 MedPAR file for ICD–9–CM diagnosis codes 414.2 and 414.4. The following table shows our findings.

SDX	SDX description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
414.2	Chronic total occlusion of coronary artery.	Non-CC	14,655	1.393	21,222	2.098	20,615	3.046
414.4	Coronary atherosclerosis due to calcified coronary lesion.	Non-CC	1,752	1.412	3,238	2.148	3,244	3.053

We ran the data using the criteria described in the FY 2008 IPPS final rule with comment period (72 FR 47169) to determine severity levels for procedures in MS–DRGs. 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 an MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is an MCC.

The table above shows that the C1 finding is 1.393 for ICD–9–CM diagnosis code 414.2 and the C1 finding is 1.412 for ICD–9–CM diagnosis code 414.4. A value close to 1.0 in the C1 field suggests that the diagnosis produces the same expected value as a non-CC. 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 that the condition is expected to consume resources more similar to an MCC than a CC or a non-CC. The C2 finding was 2.098 for ICD–9–CM diagnosis code 414.2, and the C2 finding was 2.148 for ICD–9–CM diagnosis code 414.4. A C2 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 when there is at least one other secondary diagnosis that is a CC but none that is an MCC. While the C1 value of 1.393 for ICD–9–CM diagnosis code 414.2 and the C1 value of 1.412 for ICD–9–CM diagnosis code 414.4 are above the 1.0 value for a non-CC, these values do not support the reclassification of diagnosis codes 414.2 and 414.4 to MCCs. As stated earlier, a value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or a non-CC. The C2 finding of 2.098 for ICD–9–CM diagnosis code 414.2 and the C2 finding of 2.148 for ICD–9–CM diagnosis code 414.4 also do not support reclassifying these diagnosis codes to MCCs.

Our clinical advisors reviewed the data and evaluated these conditions. They recommended that we not change the severity level of diagnosis codes 414.2 and 414.4 from a non-CC to an MCC. Our clinical advisors did not believe that these diagnoses would increase the severity of illness level of patients. Considering the C1 and C2 ratings of both diagnosis codes 414.2 and 414.4 and the input from our clinical advisors, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24399 through 24400), we did not propose to reclassify conditions represented by diagnosis codes 414.2 and 414.4 to MCCs. We proposed to maintain both of these conditions as non-CCs. As stated earlier, the equivalent ICD–10–CM codes for these conditions are codes I25.82 and I25.84, respectively. Therefore, based on the data and clinical analysis, we proposed to maintain ICD–10–CM diagnosis codes I25.82 and I25.84 as non-CCs. We invited public comments on our proposals.

Comment: A number of commenters supported the proposals to maintain the designation of ICD–10–CM diagnosis codes I25.82 and I25.84 as non-CCs. The commenters stated that the proposals were reasonable, given the information that was provided.

One commenter disagreed with the proposal to maintain code I25.84 as a non-CC. The commenter indicated that it was not able to duplicate the results of C1 and C2 described in the narrative and the table presented in the proposed rule, despite contacting CMS for assistance in running the data. The commenter disagreed with the CMS' clinical advisors that the ICD–9–CM code 414.4 and ICD–10–CM code I25.84 represent conditions that are not at the MCC level. The commenter stated that patients with severe calcified lesions are more difficult to treat and, therefore, require greater resources. The commenter also expressed concerns that hospitals were underreporting cases of patients with calcified lesions.

Response: We appreciate the commenters' support for our proposals. In response to the commenter who disagreed with our clinical advisors' determination that ICD–9–CM code 414.4 and ICD–10–CM code I25.84 represent conditions that are not at the MCC level, we point out that ICD–9–CM code 414.4 captures patients who are diagnosed as having coronary atherosclerosis due to calcified coronary lesions. This diagnosis code includes patients with any range of calcified lesion, not just those with severe calcified lesions. Therefore, the use of ICD–9–CM code 414.4 is not restricted to those patients who have severe calcified lesions. Hospitals are correctly using this code to report all patients who are determined to have atherosclerosis due to calcified coronary lesions. The same is true for the use of ICD–10–CM code I25.84, which is not restricted to cases with severe calcified

lesions. We based our analysis on claims data reported by hospitals. We cannot speculate on the underreporting of this condition on submitted claims. It also appears that the commenter did not follow the correct methodology in attempting to replicate the results for C1 and C2. 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 use the same cost calculations for computing the C1, C2, and C3 values that we use in calculating the relative weights. The cases for each ''C'' statistic are the cases with the secondary diagnosis codes for all the cases in that subset of non-CC cases, CC cases, or MCC cases. For example, the cases that are in the C3 statistic are those cases with one or more MCC secondary diagnosis codes in addition to the secondary diagnosis code under the specific review. Cases that are in the C2 statistic are those cases that do not have any MCC secondary diagnosis codes, but have one or more CC secondary diagnosis codes in addition to the secondary diagnosis code under review. The remaining cases are in the C1 statistic and have only non-CC secondary diagnosis codes along with the secondary diagnosis code under review. 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 major CC subgroup.
4	Significantly above the expected value for the major CC 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 of cases in that subset. An expected average cost is computed across all cases in the data analysis for each base MS–DRG and severity level (1=MCC, 2=CC, and 3=Non-CC). Then, for each case in a subset, the average expected cost is computed based on the base MS–DRG and severity level to which the cases are assigned. The following format was used to evaluate each diagnosis:

Code Diagnosis Cnt1 C1 Cnt2 C2 Cnt3 C3

Where 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. A C1 value of 1.412 for a secondary diagnosis code 414.4 (Coronary atherosclerosis due to calcified coronary lesion) 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 41.2 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).

After consideration of the public comments we received, the findings from our claims data, and the input from our clinical advisors noted above, we are finalizing our proposal to maintain ICD–10–CM diagnosis codes I25.82 and I25.84 as non-CCs.

c. Hydronephrosis

Some ICD–10–CM diagnosis codes express conditions that are normally coded in ICD–9–CM using two or more ICD–9–CM diagnosis codes. CMS' goal in developing the ICD–10 MS–DRGs was to ensure that a patient case is assigned to the same MS–DRG, regardless of whether the patient record were to be coded in ICD–9–CM or ICD–10–CM/PCS. When one of the ICD–10–CM combination codes is used as a principal diagnosis, the cluster of ICD–9–CM codes that would be coded on an ICD–9–CM record was evaluated. If one of the ICD–9–CM codes in the cluster is a CC or an MCC, the single ICD–10–CM combination code used as a principal diagnosis also must imply that the CC or MCC is present. Appendix J of the ICD–10 MS–DRG Definitions Manual Version 32 includes two lists. Part 1 is the list of principal diagnosis codes where the ICD–10–CM code is its own MCC. Part 2 is the list of principal diagnosis codes where the ICD–10–CM code is its own CC. Appendix J of the ICD–10 MS–DRG Definitions Manual Version 32 is available via the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*.

We received a request that the ICD–10–CM combination codes for hydronephrosis due to ureteral stricture and urinary stone (N13.1 and N13.2) be flagged as principal diagnoses that can act as their own CC for MS–DRG grouping purposes.

In ICD–9–CM, code 591 (Hydronephrosis) is classified as a CC. In ICD–10–CM, hydronephrosis is reported with a combination code if the hydronephrosis is due to a ureteral stricture or urinary stone obstruction of N13.1 (Hydronephrosis with ureteral stricture, not elsewhere classified) and N13.2 (Hydronephrosis with renal and ureteral calculous obstruction). In ICD–10–CM, these two codes (N13.1 and N 13.2) are classified as CCs, but these codes are not recognized as principal diagnoses that act as their own CC (they are not included in the Appendix J of the ICD–10 MS–DRG Definitions Manual Version 32).

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24400), we stated that we agreed with the requestor that ICD–10–CM diagnosis codes N13.1 and N13.2 should be flagged as principal diagnosis codes that can act as their own CC for MS–DRG grouping purposes. Therefore, we proposed that diagnosis codes N13.1 and N13.2 be added to the list of principal diagnoses that act as their own CC in Appendix J of the ICD–10 MS–DRG Definitions Manual Version 33. We invited public comments on our proposal.

Comment: A number of commenters supported the proposal. The commenters stated that the proposal was reasonable, given the data and information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add diagnosis codes N13.1 and N13.2 to the list of principal diagnoses that can act as their own CC in Appendix J of the ICD–10 MS–DRG Definitions Manual Version 33.

11. Complications or Comorbidity (CC) Exclusions List for FY 2016

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. CC Exclusions List for FY 2016

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. As we indicated above, we developed a list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

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.[6]

The ICD–10 MS–DRGs Version 32 CC Exclusion List is included as Appendix C in the Definitions Manual available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24401), we did not propose any changes to the CC Exclusion List for FY 2016. Because we did not propose any changes to the ICD–10 MS–DRGs CC Exclusion List for FY 2016, we did not publish Table 6G (Additions to the CC Exclusion List) or Table 6H (Deletions from the CC Exclusion List). We developed Table 6K (Complete List of CC Exclusions), which is available only via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Because of the length of Table 6K, we did not publish it in the Addendum to the proposed rule.

As we did for the proposed rule, because we are not making any changes to the ICD–10 MS–DRGs CC Exclusion List for FY 2016, we are not publishing Table 6G (Additions to the CC Exclusion List) or Table 6H (Deletions from the CC Exclusion List). We developed Table 6K (Complete List of CC Exclusions), which is available only via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Because of the length of Table 6K, we are not publishing it in the Addendum to this final rule. Each of the secondary diagnosis codes for which there is an exclusion is listed in Part 1 of Table 6K. Each of these secondary diagnosis codes is indicated as a CC or an MCC. If the CC or MCC is allowed with all principal diagnoses, the phrase ''NoExcl'' (for no exclusions) follows the CC/MCC indicator. Otherwise, a link is given to a collection of diagnosis codes which, when used as the principal diagnosis, will cause the CC or MCC to be considered as only a non-CC. Part 2 of Table 6K lists codes that are assigned as an MCC only for patients discharged alive. Otherwise, the codes are assigned as a non-CC.

A complete updated MCC, CC, and Non-CC Exclusions List is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Because there are no new, revised, or deleted ICD–10–CM diagnosis codes for FY 2016, we have not developed Table 6A (New Diagnosis Codes), Table 6C (Invalid Diagnosis Codes), or Table 6E (Revised Diagnosis Code Titles), for this final rule and they are not published as part of this final rule. We have developed Table 6B (New Procedure Codes) for new ICD–10–PCS codes which will be implemented on October 1, 2015. Because there are no revised or

[6] We refer readers to the FY 1989 final rule (53 FR 38485, September 30, 1988) for the revision made for the discharges occurring in FY 1989; the FY 1990 final rule (54 FR 36552, September 1, 1989) for the FY 1990 revision; the FY 1991 final rule (55 FR 36126, September 4, 1990) for the FY 1991 revision; the FY 1992 final rule (56 FR 43209, August 30, 1991) for the FY 1992 revision; the FY 1993 final rule (57 FR 39753, September 1, 1992) for the FY 1993 revision; the FY 1994 final rule (58 FR 46278, September 1, 1993) for the FY 1994 revisions; the FY 1995 final rule (59 FR 45334, September 1, 1994) for the FY 1995 revisions; the FY 1996 final rule (60 FR 45782, September 1, 1995) for the FY 1996 revisions; the FY 1997 final rule (61 FR 46171, August 30, 1996) for the FY 1997 revisions; the FY 1998 final rule (62 FR 45966, August 29, 1997) for the FY 1998 revisions; the FY 1999 final rule (63 FR 40954, July 31, 1998) for the FY 1999 revisions; the FY 2001 final rule (65 FR 47064, August 1, 2000) for the FY 2001 revisions; the FY 2002 final rule (66 FR 39851, August 1, 2001) for the FY 2002 revisions; the FY 2003 final rule (67 FR 49998, August 1, 2002) for the FY 2003 revisions; the FY 2004 final rule (68 FR 45364, August 1, 2003) for the FY 2004 revisions; the FY 2005 final rule (69 FR 49848, August 11, 2004) for the FY 2005 revisions; the FY 2006 final rule (70 FR 47640, August 12, 2005) for the FY 2006 revisions; the FY 2007 final rule (71 FR 47870) for the FY 2007 revisions; the FY 2008 final rule (72 FR 47130) for the FY 2008 revisions; the FY 2009 final rule (73 FR 48510); the FY 2010 final rule (74 FR 43799); the FY 2011 final rule (75 FR 50114); the FY 2012 final rule (76 FR 51542); the FY 2013 final rule (77 FR 53315); the FY 2014 final rule (78 FR 50541), and the FY 2015 final rule (79 FR 49905). In the FY 2000 final rule (64 FR 41490, July 30, 1999), we did not modify the CC Exclusions List because we did not make any changes to the ICD–9–CM codes for FY 2000.

deleted procedure codes for FY 2016, we have not developed Table 6D (Invalid Procedure Codes) or Table 6F (Revised Procedure Codes).

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24401), we did not propose any additions or deletions to the MS–DRG MCC List for FY 2016 nor any additions or deletions to the MS–DRG CC List for FY 2016. As we did for the proposed rule, for this final rule, we have not developed Tables 6I.1 (Additions to the MCC List), 6I.2 (Deletions to the MCC List), 6J.1 (Additions to the CC List), and 6J.2 (Deletions to the CC List), and they are not published as part of this final rule. We have developed Tables 6L (Principal Diagnosis Is Its Own MCC List) and 6M (Principal Diagnosis Is Its Own CC List). As stated in the Definitions Manual of the ICD–10 MS DRGs Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*, 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 place a patient in the same DRG, 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 an MCC, 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 in these tables. We also have developed Table 6M.1 (Additions to Principal Diagnosis Is Its Own CC) to show the two additions to this list for the two principal diagnosis codes acting as their own CC.

The complete documentation of the ICD–10 MS–DRG Version 32 GROUPER logic, including the current CC Exclusions List, is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. The complete documentation of the ICD–10 MS–DRG GROUPER logic also is available on the CMS Acute Inpatient PPS Web page at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

12. Review of Procedure Codes in MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989

Each year, we review cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS–DRGs that we adopted for FY 2008, CMS DRG 468 was split three ways and became MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 476 became MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 477 became MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

MS–DRGs 981 through 983, 984 through 986, and 987 through 989 (formerly CMS DRGs 468, 476, and 477, respectively) 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. MS–DRGs 984 through 986 (previously CMS DRG 476) are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0 (Incision of prostate);
- 60.12 (Open biopsy of prostate);
- 60.15 (Biopsy of periprostatic tissue);
- 60.18 (Other diagnostic procedures on prostate and periprostatic tissue);
- 60.21 (Transurethral prostatectomy);
- 60.29 (Other transurethral prostatectomy);
- 60.61 (Local excision of lesion of prostate);
- 60.69 (Prostatectomy, not elsewhere classified);
- 60.81 (Incision of periprostatic tissue);
- 60.82 (Excision of periprostatic tissue);
- 60.93 (Repair of prostate);
- 60.94 (Control of (postoperative) hemorrhage of prostate);
- 60.95 (Transurethral balloon dilation of the prostatic urethra);
- 60.96 (Transurethral destruction of prostate tissue by microwave thermotherapy);
- 60.97 (Other transurethral destruction of prostate tissue by other thermotherapy); and
- 60.99 (Other operations on prostate).

All remaining O.R. procedures are assigned to MS–DRGs 981 through 983 and 987 through 989, with MS–DRGs 987 through 989 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.[7]

Our review of MedPAR claims data showed that there are no cases that merited movement or should logically be assigned to any of the other MDCs. Therefore, for FY 2016, we did not propose to change the procedures assigned among these MS–DRGs. We invited public comments on our proposal.

We did not receive any public comments on our proposal and, therefore, are adopting it as final.

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

[7] The original list of the ICD–9–CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the FY 1989 final rule (53 FR 38591). As part of the FY 1991 final rule (55 FR 36135), the FY 1992 final rule (56 FR 43212), the FY 1993 final rule (57 FR 23625), the FY 1994 final rule (58 FR 46279), the FY 1995 final rule (59 FR 45336), the FY 1996 final rule (60 FR 45783), the FY 1997 final rule (61 FR 46173), and the FY 1998 final rule (62 FR 45981), we moved several other procedures from DRG 468 to DRG 477, and some procedures from DRG 477 to DRG 468. No procedures were moved in FY 1999, as noted in the final rule (63 FR 40962), in the FY 2000 (64 FR 41496), in the FY 2001 (65 FR 47064), or in the FY 2002 (66 FR 39852). In the FY 2003 final rule (67 FR 49999), we did not move any procedures from DRG 477. However, we did move procedure codes from DRG 468 and placed them in more clinically coherent DRGs. In the FY 2004 final rule (68 FR 45365), we moved several procedures from DRG 468 to DRGs 476 and 477 because the procedures are nonextensive. In the FY 2005 final rule (69 FR 48950), we moved one procedure from DRG 468 to 477. In addition, we added several existing procedures to DRGs 476 and 477. In FY 2006 (70 FR 47317), we moved one procedure from DRG 468 and assigned it to DRG 477. In FY 2007, we moved one procedure from DRG 468 and assigned it to DRGs 479, 553, and 554. In FYs 2008, 2009, 2010, 2011, 2012, 2013, 2014, and 2015, no procedures were moved, as noted in the FY 2008 final rule with comment period (72 FR 46241), in the FY 2009 final rule (73 FR 48513), in the FY 2010 final rule (74 FR 43796), in the FY 2011 final rule (75 FR 50122), in the FY 2012 final rule (76 FR 51549), in the FY 2013 final rule (77 FR 53321), in the FY 2014 final rule (78 FR 50545); and in the FY 2015 final rule (79 FR 49906).

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. As noted above, there are no cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2016, we did not propose to remove 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 invited public comments on our proposal.

We did not receive any public comments on our proposal and, therefore, are adopting it as final.

b. Reassignment of Procedures Among MS DRGs 981 Through 983, 984 Through 986, and 987 Through 989

(1) Annual Review of Procedures

We also annually review the list of ICD–9–CM procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, 984 through 986 (Prostatic O.R. procedure unrelated to principal diagnosis with MCC, with CC, or without CC/MCC, respectively), and 987 through 989, to ascertain whether any of those procedures should be reassigned from one of these three MS DRGs to another of the three 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.

There are no cases representing shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical, or that merited movement so that cases should logically be assigned to any of the other MDCs. Therefore, for FY 2016, we did not propose to move any procedure codes among these MS–DRGs.

We did not receive any public comments on our proposal and, therefore, are adopting it as final.

(2) Review of Cases With Endovascular Embolization Procedures for Epistaxis

During the comment period for the FY 2015 IPPS/LTCH PPS proposed rule, we received a public comment expressing concern regarding specific procedure codes that are assigned to MS–DRGs 981 through 983; 984 through 986; and 987 through 989 in relation to our discussion of the annual review of these MS–DRGs in section II.G.12. of that proposed rule (79 FR 28020). The commenter noted that the endovascular embolization of the arteries of the branches of the internal maxillary artery is frequently performed for intractable posterior epistaxis (nosebleed). The commenter stated that, currently, diagnosis code 784.7 (Epistaxis) reported with procedure codes 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils) and 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils) groups to MS–DRGs 981, 982, and 983. The commenter indicated that it also found this grouping with the ICD–10 MS–DRGs Version 31 using ICD–10–CM diagnosis code R04.0 (Epistaxis) reported with artery occlusion procedure codes. The commenter requested that CMS review these groupings and consider the possibility of reassigning these epistaxis cases with endovascular embolization procedure codes into a more specific MS–DRG.

We considered this public comment to be outside of the scope of the FY 2015 IPPS/LTCH PPS proposed rule and, therefore, did not address it in the FY 2015 IPPS/LTCH PPS final rule. However, we indicated that we would consider this public comment for possible proposals in future rulemaking as part of our annual review process.

ICD–10–PCS provides more detailed codes for endovascular embolization or occlusion of vessel(s) of head or neck using bare coils and bioactive coils which are listed in the following table:

ICD–10–PCS Codes for Endovascular Embolization or Occlusion of Vessel(s) of Head or Neck Using Bare Coils and Bioactive Coils

ICD–10–PCS code	Code description
03LG0BZ	Occlusion of intracranial artery with bioactive intraluminal device, open approach.
03LG0DZ	Occlusion of intracranial artery with intraluminal device, open approach.
03LG3BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous approach.
03LG3DZ	Occlusion of intracranial artery with intraluminal device, percutaneous approach.
03LG4BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LG4DZ	Occlusion of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03LH0BZ	Occlusion of right common carotid artery with bioactive intraluminal device, open approach.
03LH0DZ	Occlusion of right common carotid artery with intraluminal device, open approach.
03LH3BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03LH3DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous approach.
03LH4BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LH4DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LJ0BZ	Occlusion of left common carotid artery with bioactive intraluminal device, open approach.
03LJ0DZ	Occlusion of left common carotid artery with intraluminal device, open approach.
03LJ3BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03LJ3DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous approach.
03LJ4BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LJ4DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous endoscopic approach.

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF VESSEL(S) OF HEAD OR NECK USING BARE COILS AND BIOACTIVE COILS—Continued

ICD–10–PCS code	Code description
03LK0BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, open approach.
03LK0DZ	Occlusion of right internal carotid artery with intraluminal device, open approach.
03LK3BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LK3DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous approach.
03LK4BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LK4DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LL0BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, open approach.
03LL0DZ	Occlusion of left internal carotid artery with intraluminal device, open approach.
03LL3BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LL3DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous approach.
03LL4BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LL4DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LM0BZ	Occlusion of right external carotid artery with bioactive intraluminal device, open approach.
03LM0DZ	Occlusion of right external carotid artery with intraluminal device, open approach.
03LM3BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03LM3DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous approach.
03LM4BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LM4DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LN0BZ	Occlusion of left external carotid artery with bioactive intraluminal device, open approach.
03LN0DZ	Occlusion of left external carotid artery with intraluminal device, open approach.
03LN3BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03LN3DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous approach.
03LN4BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LN4DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LP0BZ	Occlusion of right vertebral artery with bioactive intraluminal device, open approach.
03LP0DZ	Occlusion of right vertebral artery with intraluminal device, open approach.
03LP3BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03LP3DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous approach.
03LP4BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LP4DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LQ0BZ	Occlusion of left vertebral artery with bioactive intraluminal device, open approach.
03LQ0DZ	Occlusion of left vertebral artery with intraluminal device, open approach.
03LQ3BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03LQ3DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous approach.
03LQ4BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LQ4DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VG0BZ	Restriction of intracranial artery with bioactive intraluminal device, open approach.
03VG0DZ	Restriction of intracranial artery with intraluminal device, open approach.
03VG3BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous approach.
03VG3DZ	Restriction of intracranial artery with intraluminal device, percutaneous approach.
03VG4BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VG4DZ	Restriction of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03VH0BZ	Restriction of right common carotid artery with bioactive intraluminal device, open approach.
03VH0DZ	Restriction of right common carotid artery with intraluminal device, open approach.
03VH3BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03VH3DZ	Restriction of right common carotid artery with intraluminal device, percutaneous approach.
03VH4BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VH4DZ	Restriction of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VJ0BZ	Restriction of left common carotid artery with bioactive intraluminal device, open approach.
03VJ0DZ	Restriction of left common carotid artery with intraluminal device, open approach.
03VJ3BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03VJ3DZ	Restriction of left common carotid artery with intraluminal device, percutaneous approach.
03VJ4BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VJ4DZ	Restriction of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VK0BZ	Restriction of right internal carotid artery with bioactive intraluminal device, open approach.
03VK0DZ	Restriction of right internal carotid artery with intraluminal device, open approach.
03VK3BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VK3DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous approach.
03VK4BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VK4DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VL0BZ	Restriction of left internal carotid artery with bioactive intraluminal device, open approach.
03VL0DZ	Restriction of left internal carotid artery with intraluminal device, open approach.
03VL3BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VL3DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous approach.
03VL4BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VL4DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VM0BZ	Restriction of right external carotid artery with bioactive intraluminal device, open approach.
03VM0DZ	Restriction of right external carotid artery with intraluminal device, open approach.
03VM3BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03VM3DZ	Restriction of right external carotid artery with intraluminal device, percutaneous approach.

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF VESSEL(S) OF HEAD OR NECK USING BARE COILS AND BIOACTIVE COILS—Continued

ICD–10–PCS code	Code description
03VM4BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VM4DZ	Restriction of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VN0BZ	Restriction of left external carotid artery with bioactive intraluminal device, open approach.
03VN0DZ	Restriction of left external carotid artery with intraluminal device, open approach.
03VN3BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03VN3DZ	Restriction of left external carotid artery with intraluminal device, percutaneous approach.
03VN4BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VN4DZ	Restriction of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VP0BZ	Restriction of right vertebral artery with bioactive intraluminal device, open approach.
03VP0DZ	Restriction of right vertebral artery with intraluminal device, open approach.
03VP3BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03VP3DZ	Restriction of right vertebral artery with intraluminal device, percutaneous approach.
03VP4BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VP4DZ	Restriction of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VQ0BZ	Restriction of left vertebral artery with bioactive intraluminal device, open approach.
03VQ0DZ	Restriction of left vertebral artery with intraluminal device, open approach.
03VQ3BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03VQ3DZ	Restriction of left vertebral artery with intraluminal device, percutaneous approach.
03VQ4BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VQ4DZ	Restriction of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VR0DZ	Restriction of face artery with intraluminal device, open approach.
03VR3DZ	Restriction of face artery with intraluminal device, percutaneous approach.
03VR4DZ	Restriction of face artery with intraluminal device, percutaneous endoscopic approach.
03VS0DZ	Restriction of right temporal artery with intraluminal device, open approach.
03VS3DZ	Restriction of right temporal artery with intraluminal device, percutaneous approach.
03VS4DZ	Restriction of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03VT0DZ	Restriction of left temporal artery with intraluminal device, open approach.
03VT3DZ	Restriction of left temporal artery with intraluminal device, percutaneous approach.
03VT4DZ	Restriction of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VU0DZ	Restriction of right thyroid artery with intraluminal device, open approach.
03VU3DZ	Restriction of right thyroid artery with intraluminal device, percutaneous approach.
03VU4DZ	Restriction of right thyroid artery with intraluminal device, percutaneous endoscopic approach.
03VV0DZ	Restriction of left thyroid artery with intraluminal device, open approach.
03VV3DZ	Restriction of left thyroid artery with intraluminal device, percutaneous approach.
03VV4DZ	Restriction of left thyroid artery with intraluminal device, percutaneous endoscopic approach.

We examined claims data from the December 2014 update of the FY 2014 MedPAR file for cases with diagnosis code 784.7 reported with procedure codes 39.75 and 39.76 in MS–DRGs 981, 982, and 983. The following table shows our findings.

ENDOVASCULAR EMBOLIZATION PROCEDURES FOR EPISTAXIS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—All cases	21,118	12.38	$33,080
MS–DRG 981—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.75	8	6.50	34,655
MS–DRG 981—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.76	2	12.50	50,081
MS–DRG 982—All cases	13,657	7.14	19,392
MS–DRG 982—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.75	22	3.14	17,725
MS–DRG 982—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.76	2	2.0	11,010
MS–DRG 983—All cases	2,989	3.60	12,760
MS–DRG 983—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.75	5	2.60	10,532
MS–DRG 983—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.76	4	1.50	16,658

We found only 35 epistaxis cases with procedure code 39.75 reported and 8 cases with procedure code 39.76 reported among MS–DRGs 981, 982, and 983. The use of endovascular embolizations for epistaxis appears to be rare. The average costs for the cases with procedure code 39.75 in MS–DRGs 981, 982, and 983 are similar to the average costs for all cases in MS–DRGs 981, 982, and 983, respectively. The average costs for the cases with procedure code 39.75 in MS–DRGs 981, 982, and 983 were $34,655, $17,725, and $10,532, respectively, compared to $33,080, $19,392, and $12,760 for all cases in MS–DRGs 981, 982, and 983. The average costs for cases with procedure code 39.76 in MS–DRGs 981, 982, and 983 were $50,081, $11,010, and $16,658, respectively, and were significantly greater than all cases in MS–DRGs 981 and 983. However, as stated earlier, there were only 8 cases reported with procedure code 39.76. As explained previously, MS–DRGs 981, 982, and 983 were created for operating

room procedures that are unrelated to the principal diagnosis. Because there were so few cases reported, this does not appear to be a common procedure for epistaxis. There were not enough cases to base a change of MS–DRG assignment for these cases.

Our clinical advisors reviewed this issue and did not identify any new MS–DRG assignment that would be more appropriate for these rare cases. They advised us to maintain the current MS–DRG structure within MS–DRGs 981, 982, and 983.

Based on the results of the examination of the claims data and the recommendations from our clinical advisors, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24403 through 24405), we did not propose to create new MS–DRG assignments for epistaxis cases receiving endovascular embolization procedures. We proposed to maintain the current MS–DRG structure for epistaxis cases receiving endovascular embolization procedures and did not propose any updates to MS–DRGs 981, 982, and 983. We invited public comments on our proposal.

Comment: A number of commenters supported the proposal. The commenters stated that the proposal was reasonable, given the data and information provided.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current MS–DRG structure for epistaxis cases receiving endovascular embolization procedures and not make any updates to MS–DRGs 981, 982, and 983.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs, as described above in sections II.G.2. through 7. of the preamble of this final rule, we did not propose to add any diagnosis or procedure codes to MDCs for FY 2016. We invited public comments on our proposal.

We did not receive any public comments on our proposal and, therefore, are adopting it as final.

13. Changes to the ICD–9–CM System

a. ICD–10 Coordination and Maintenance Committee

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, and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was to be 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, ICD–10–PCS, and ICD–9–CM 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 Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html.* The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS Web site 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 above 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 2016 at a public meeting held on September 23–24, 2014, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 15, 2014.

The Committee held its 2015 meeting on March 18–19, 2015. 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 2015 would be included in the October 1, 2015 update to ICD–10–CM/ICD–10–PCS. For FY 2016, there are no new, revised, or deleted ICD–10–CM diagnosis codes. For FY 2016, there are new ICD–10–PCS procedure codes that are included in Table 6B (New Procedure Codes). However, there are no revised or deleted ICD–10–PCS procedure codes. There also are no new ICD–9–CM diagnosis or procedure codes because ICD–9–CM will be replaced by ICD–10–CM/ICD–10–PCS for services provided on or after October 1, 2015.

Copies of the agenda, handouts, and access to the live stream videos for the procedure codes discussions at the Committee's September 23–24, 2014 meeting and March 18–19, 2015 meeting can be obtained from the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03_meetings.asp.* The agenda, handouts and minutes of the diagnosis codes discussions at the September 23–24, 2014 meeting and March 18–19, 2015 meeting are found at: *http://www.cdc.gov/nchs/icd/icd9cm-maintenance.html.* These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, 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 Email to: *dfp4@cdc.gov.*

Questions and comments concerning the procedure codes should be addressed to: Patricia Brooks, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, CMS, Center for Medicare, Hospital and Ambulatory Policy Group, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments may be sent by Email to: *patricia.brooks2@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 ICD–9–CM 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 system 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 Web site. The public decides whether or not to attend the meeting based on the topics listed on the agenda. 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 Web sites in May 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 new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requestor at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting 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 no requests approved for an expedited April l, 2015 implementation of a code at the September 23–24, 2014 Committee meeting. Therefore, there were no new codes implemented on April 1, 2015.

ICD–9–CM addendum and code title information is published on the CMS Web site at: *http://www.cms.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 Web site at *http://www.cms.gov/Medicare/Coding/ICD10/index.html*. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC Web site at: *http://www.cdc.gov/nchs/index.html*. Information on new, revised, and deleted ICD–10–CM/ICD–10–PCS codes is also provided to the AHA for publication in the *Coding Clinic for ICD–10.* AHA also distributes information to publishers and software vendors.

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.

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.

b. Code Freeze

In the January 16, 2009 ICD–10–CM and ICD–10–PCS final rule (74 FR 3340), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD–9–CM and ICD–10–CM and ICD–10–PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease l year prior to the implementation of ICD–10. The commenters stated that this freeze of code updates would allow for instructional and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place immediately before the compliance date, necessitating additional updates and purchases.

HHS responded to comments in the ICD–10 final rule that the ICD–9–CM Coordination and Maintenance Committee has jurisdiction over any action impacting the ICD–9–CM and ICD–10 code sets. Therefore, HHS indicated that the issue of consideration of a moratorium on updates to the ICD–9–CM, ICD–10–CM, and ICD–10–PCS code sets in anticipation of the adoption of ICD–10–CM and ICD–10–PCS would be addressed through the Committee at a future public meeting.

The code freeze was discussed at multiple meetings of the ICD–9–CM Coordination and Maintenance

Committee and public comment was actively solicited. The Committee evaluated all comments from participants attending the Committee meetings as well as written comments that were received. The Committee also considered the delay in implementation of ICD–10 until October 1, 2014. There was an announcement at the September 19, 2012 ICD–9–CM Coordination and Maintenance Committee meeting that a partial freeze of both ICD–9–CM and ICD–10 codes will be implemented as follows:

- The last regular annual update to both ICD–9–CM and ICD–10 code sets was made on October 1, 2011.
- On October 1, 2012 and October 1, 2013, there were to be only limited code updates to both ICD–9–CM and ICD–10 code sets to capture new technology and new diseases.
- On October 1, 2014, there were to be only limited code updates to ICD–10 code sets to capture new technology and diagnoses as required by section 503(a) of Public Law 108–173. There were to be no updates to ICD–9–CM on October 1, 2014.
- On October 1, 2015, one year after the originally scheduled implementation of ICD–10, regular updates to ICD–10 were to begin.

On May 15, 2014, CMS posted an updated Partial Code Freeze schedule on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-9-CM-Coordination-and-Maintenance-Committee-Meetings.html*. This updated schedule provided information on the extension of the partial code freeze until 1 year after the implementation of ICD–10. As stated earlier, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included a new compliance date that requires the use of ICD–10 beginning October 1, 2015. The August 4, 2014 final rule is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2014-08-04/pdf/2014-18347.pdf*. That final rule also requires HIPAA covered entities to continue to use ICD–9–CM through September 30, 2015. Accordingly, the updated schedule for the partial code freeze is as follows:

- The last regular annual updates to both ICD–9–CM and ICD–10 code sets were made on October 1, 2011.
- On October 1, 2012, October 1, 2013, and October 1, 2014, there were only limited code updates to both the ICD–9–CM and ICD–10 code sets to capture new technologies and diseases as required by section 1886(d)(5)(K) of the Act.
- On October 1, 2015, there will be only limited code updates to ICD–10 code sets to capture new technologies and diagnoses as required by section 1886(d)(5)(K) of the Act. There will be no updates to ICD–9–CM, as it will no longer be used for reporting.
- On October 1, 2016 (1 year after implementation of ICD–10), regular updates to ICD–10 will begin.

The ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee announced that it would continue to meet twice a year during the freeze. At these meetings, the public will be encouraged to comment on whether or not requests for new diagnosis and procedure codes should be created based on the need to capture new technology and new diseases. Any code requests that do not meet the criteria will be evaluated for implementation within ICD–10 one year after the implementation of ICD–10, once the partial freeze is ended.

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD–10 Coordination and Maintenance Committee Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html*. A summary of the September 19, 2012 Committee meeting, along with both written and audio transcripts of this meeting, is posted on the Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2012-09-19-MeetingMaterials.html*.

This partial code freeze has dramatically decreased the number of codes created each year as shown by the following information.

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR

ICD–9–CM Codes			ICD–10–CM and ICD–10–PCS Codes		
Fiscal Year	Number	Change	Fiscal Year	Number	Change
FY 2009 (October 1, 2008):			FY 2009:		
Diagnoses	14,025	348	ICD–10–CM	68,069	+5
Procedures	3,824	56	ICD–10–PCS	72,589	−14,327
FY 2010 (October 1, 2009):			FY 2010:		
Diagnoses	14,315	290	ICD–10–CM	69,099	+1,030
Procedures	3,838	14	ICD–10–PCS	71,957	−632
FY 2011 (October 1, 2010):					
Diagnoses	14,432	117	ICD–10–CM	69,368	+269
Procedures	3,859	21	ICD–10–PCS	72,081	+124
FY 2012 (October 1, 2011):			FY 2012:		
Diagnoses	14,567	135	ICD–10–CM	69,833	+465
Procedures	3,877	18	ICD–10–PCS	71,918	−163
FY 2013 (October 1, 2012):			FY 2013:		
Diagnoses	14,567	0	ICD–10–CM	69,832	−1
Procedures	3,878	1	ICD–10–PCS	71,920	+2
FY 2014 (October 1, 2013):			FY 2014:		
Diagnoses	14,567	0	ICD–10–CM	69,823	−9
Procedures	3,882	4	ICD–10–PCS	71,924	+4
FY 2015 (October 1, 2014):			FY 2015:		
Diagnoses	14,567	0	ICD–10–CM	69,823	0
Procedures	3,882	0	ICD–10–PCS	71,924	0
FY 2016 (October 1, 2015):			FY 2016:		
Diagnoses	14,567	0	ICD–10–CM	69,823	0
Procedures	3,882	0	ICD–10–PCS	71,974	+50

As mentioned earlier, 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. The public has supported only a limited number of new codes during the partial code freeze, as can be seen by data shown above. We have gone from creating several hundred new codes each year to creating only a limited number of new ICD–9–CM and ICD–10 codes.

At the September 23–24, 2014 and March 18–19, 2015 Committee meetings, we discussed any requests we had received for new ICD–10–CM diagnosis and ICD–10–PCS procedure codes that were to be implemented on October 1, 2015. We did not discuss ICD–9–CM codes. The public was given the opportunity to comment on whether or not new ICD–10–CM and ICD–10–PCS codes should be created, based on the partial code freeze criteria. The public was to use the criteria as to whether codes were needed to capture new diagnoses or new technologies. If the codes do not meet those criteria for implementation during the partial code freeze, consideration was to be given as to whether the codes should be created after the partial code freeze ends 1 year after the implementation of ICD–10–CM/PCS. We invited public comments on any code requests discussed at the September 23–24, 2014 and March 18–19, 2015 Committee meetings for implementation as part of the October 1, 2015 update. The deadline for commenting on code proposals discussed at the September 23–24, 2014 Committee meeting was November 21, 2014. The deadline for commenting on code proposals discussed at the March 18–19, 2015 Committee meeting was April 17, 2015.

14. Other Policy Changes: 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 has been recalled determined the base MS–DRG assignment. We specified that if a hospital received a credit for a recalled device equal to 50 percent or more of the cost of the device, we would reduce a hospital's IPPS payment for those MS–DRGs.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 and 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. Request for Clarification on Policy Relating to ''Device-Dependent'' MS–DRGs

After publication of the FY 2015 IPPS/LTCH PPS final rule, we received a request to clarify the list of ''device-dependent'' MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit. Specifically, a requestor noted that ICD–9–CM procedure codes that previously grouped to MS–DRGs 216 through 221 (Cardiac Valve & Other Major Cardiothoracic Procedure with and without Cardiac Catheterization, with MCC, with CC, without CC/MCC, respectively) and were subject to the policy for payment under the IPPS as ''device-dependent'' MS–DRGs had been reassigned to new MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with MCC and without MCC, respectively). The requestor suggested that MS–DRGs 266 and 267 also should be considered ''device-dependent'' MS–DRGs and added to the list of MS–DRGs subject to the IPPS payment policy for replaced devices offered without cost or with a credit.

As noted by the requestor, as final policy for FY 2015, certain ICD–9–CM procedure codes that previously grouped to MS–DRGs 216 through 221, which are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit, were reassigned to MS–DRGs 266 and 267. We agree that MS–DRGs 266 and 267 should be included in the list of ''device-dependent'' MS–DRGs subject to the IPPS policy. We generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24409), we proposed to add MS–DRGs 266 and 267 to the list of ''device dependent'' MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit.

In addition, as discussed in section II.G.4.e. of the preamble of the proposed rule, for FY 2016, we proposed to delete MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively) and create new MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC and without MCC, respectively), as well as new MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively). Currently, MS–DRGs 237 and 238 are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit. As stated previously, we generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Therefore, we indicated that if we finalized these proposed MS–DRG changes, we also would add proposed new MS–DRGs 268 through 272 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit. We invited public comments on our proposed list of MS–DRGs to be subject to the IPPS policy for replaced devices offered without cost or with a credit for FY 2016 (80 FR 24409 through 24410).

Comment: Commenters supported the proposal to add MS–DRGs 266 and 267 to the list of MS–DRGs subject to the IPPS payment policy for replaced devices offered without cost or with a credit. We did not receive any public comments in response to our proposal to delete ICD–9–CM MS–DRGs 237 and 238 and add any of the finalized new ICD–10 MS–DRGs to the list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are adding MS–DRGs 266 and 267 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit, and consistent with the applicable finalized MS–DRG changes, also removing existing MS–DRGs 237 and 238 and adding new MS–DRGs 268 through 272. The list of MS–DRGs that are subject to the IPPS policy for replaced devices offered without cost or with a credit for FY 2016 is displayed below. We also intend to issue this list to providers in the form of a Change Request (CR).

LIST OF MS–DRGS SUBJECT TO THE IPPS POLICY FOR REPLACED DEVICES OFFERED WITHOUT COST OR WITH A CREDIT

MDC	MS–DRG	MS–DRG title
PreMDC	001	Heart Transplant or Implant of Heart Assist System with MCC.
PreMDC	002	Heart Transplant or Implant of Heart Assist System without MCC.
MDC 01	023	Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant.
MDC 01	024	Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC.
MDC 01	025	Craniotomy & Endovascular Intracranial Procedures with MCC.
MDC 01	026	Craniotomy & Endovascular Intracranial Procedures with CC.
MDC 01	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC.
MDC 01	040	Peripheral/Cranial Nerve & Other Nervous System Procedures with MCC.
MDC 01	041	Peripheral/Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulation.
MDC 01	042	Peripheral/Cranial Nerve & Other Nervous System Procedures without CC/MCC.
MDC 03	129	Major Head & Neck Procedures with CC/MCC or Major Device.
MDC 03	130	Major Head & Neck Procedures without CC/MCC.
MDC 05	215	Other Heart Assist System Implant.
MDC 05	216	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC.
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC.
MDC 05	218	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC.
MDC 05	219	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC.
MDC 05	220	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC.
MDC 05	221	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC.
MDC 05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC.
MDC 05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC.
MDC 05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC.
MDC 05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC.
MDC 05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC.
MDC 05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC.
MDC 05	242	Permanent Cardiac Pacemaker Implant with MCC.
MDC 05	243	Permanent Cardiac Pacemaker Implant with CC.
MDC 05	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
MDC 05	245	AICD Generator Procedures.
MDC 05	258	Cardiac Pacemaker Device Replacement with MCC.
MDC 05	259	Cardiac Pacemaker Device Replacement without MCC.
MDC 05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
MDC 05	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
MDC 05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
MDC 05	265	AICD Lead Procedures.
MDC 05	266	Endovascular Cardiac Valve Replacement with MCC.
MDC 05	267	Endovascular Cardiac Valve Replacement without MCC.
MDC 05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
MDC 05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
MDC 05	270	Other Major Cardiovascular Procedures with MCC.
MDC 05	271	Other Major Cardiovascular Procedures with CC.
MDC 05	272	Other Major Cardiovascular Procedures without CC/MCC.
MDC 08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC.
MDC 08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
MDC 08	466	Revision of Hip or Knee Replacement with MCC.
MDC 08	467	Revision of Hip or Knee Replacement with CC.
MDC 08	468	Revision of Hip or Knee Replacement without CC/MCC.
MDC 08	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC.
MDC 08	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC.

15. Out of Scope Public Comments

We received public comments regarding two MS–DRG issues that were outside of the scope of the proposals included in the FY 2016 IPPS/LTCH proposed rule. These comments were as follows:

- Several commenters requested the creation of a new MS–DRG for primary total ankle replacements and revisions of total ankle replacement procedures.
- Several commenters requested the creation of a new MS–DRG for hip fractures for individuals who receive total hip replacements.

However, because we consider these public comments to be outside of the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.G.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classification to submit these comments no later than December 7 of each year so that they can be considered for possible inclusion in the annual proposed rule and, if included, may be subjected to public review and comment. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

H. Recalibration of the FY 2016 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

In developing the FY 2016 system of weights, we used 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 2014 MedPAR data used in this final rule include discharges occurring on October 1, 2013, through September 30, 2014, based on bills received by CMS through March 31,

2015, 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 2014 MedPAR file used in calculating the relative weights includes data for approximately 9,682,319 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 March 31, 2015 update of the FY 2014 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 relative weights for FY 2016 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 FY 2016 relative weights are based on the ICD–9–CM diagnoses and procedures codes from the MedPAR claims data, grouped through the ICD–9–CM version of the FY 2016 GROUPER (Version 33).

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 March 31, 2015 update of the FY 2013 HCRIS for calculating the FY 2016 cost-based relative weights.

2. Methodology for Calculation of the Relative Weights

As we explain in section II.E.2. of the preamble of this final rule, we calculated the FY 2016 relative weights based on 19 CCRs, as we did for FY 2015. The methodology we used to calculate the FY 2016 MS–DRG cost-based relative weights based on claims data in the FY 2014 MedPAR file and data from the FY 2013 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the FY 2016 MS–DRG classifications discussed in sections II.B. and II.G. of the preamble of this final rule.
- The transplant cases that were used to establish the 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 2014 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 $10.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, special 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 charges, and anesthesia charges were also deleted.
- At least 92.1 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 (that is, as if hospitals were not participating in those models under the BPCI initiative). The BPCI initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. For FY 2016, as we proposed, we are continuing to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

Once the MedPAR data were trimmed and the statistical outliers were removed, the charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2013 cost report data.

The 19 cost centers that we used in the 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 19 national cost center CCRs.

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, Columns 6 and 7 and line number) Form CMS–2552–10	Medicare charges from HCRIS (Worksheet D-3, Column and 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–019X				
	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
			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 C_1_C7_64	D3_HOS_C2_64
			Drugs Charged To Patient.	C_1_C5_73	C_1_C6_73 C_1_C7_73	D3_HOS_C2_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 C_1_C7_71	D3_HOS_C2_71
	Durable Medical Equipment Charges.	0290, 0291, 0292 and 0294–0299.	DME-Rented	C_1_C5_96	C_1_C6_96 C_1_C7_96	D3_HOS_C2_96
	Used Durable Medical Charges.	0293	DME-Sold	C_1_C5_97	C_1_C6_97 C_1_C7_97	D3_HOS_C2_97
Implantable Devices		0275, 0276, 0278, 0624	Implantable Devices Charged to Patients.	C_1_C5_72	C_1_C6_72 C_1_C7_72	D3_HOS_C2_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, Columns 6 and 7 and line number) Form CMS–2552–10	Medicare charges from HCRIS (Worksheet D-3, Column and line number) Form CMS–2552–10
Therapy Services ...	Physical Therapy Charges.	042X	Physical Therapy ...	C_1_C5_66	C_1_C6_66 C_1_C7_66	D3_HOS_C2_66
	Occupational Therapy Charges.	043X	Occupational Therapy.	C_1_C5_67	C_1_C6_67 C_1_C7_67	D3_HOS_C2_67
	Speech Pathology Charges.	044X and 047X	Speech Pathology	C_1_C5_68	C_1_C6_68 C_1_C7_68	D3_HOS_C2_68
Inhalation Therapy	Inhalation Therapy Charges.	041X and 046X	Respiratory Therapy.	C_1_C5_65	C_1_C6_65 C_1_C7_65	D3_HOS_C2_65
Operating Room	Operating Room Charges.	036X	Operating Room	C_1_C5_50	C_1_C6_50 C_1_C7_50	D3_HOS_C2_50
		071X	Recovery Room	C_1_C5_51	C_1_C6_51 C_1_C7_51	D3_HOS_C2_51
Labor & Delivery	Operating Room Charges.	072X	Delivery Room and Labor Room.	C_1_C5_52	C_1_C6_52 C_1_C7_52	D3_HOS_C2_52
Anesthesia	Anesthesia Charges.	037X	Anesthesiology	C_1_C5_53	C_1_C6_53 C_1_C7_53	D3_HOS_C2_53
Cardiology	Cardiology Charges.	048X and 073X	Electrocardiology ...	C_1_C5_69	C_1_C6_69 C_1_C7_69	D3_HOS_C2_69
Cardiac Catheterization.	.....	0481	Cardiac Catheterization.	C_1_C5_59	C_1_C6_59 C_1_C7_59	D3_HOS_C2_59
Laboratory	Laboratory Charges.	030X, 031X, and 075X	Laboratory	C_1_C5_60	C_1_C6_60 C_1_C7_60	D3_HOS_C2_60
			PBP Clinic Laboratory Services.	C_1_C5_61	C_1_C6_61 C_1_C7_61	D3_HOS_C2_61
		074X, 086X	Electro-Encephalography.	C_1_C5_70	C_1_C6_70 C_1_C7_70	D3_HOS_C2_70
Radiology	Radiology Charges.	032X, 040X	Radiology—Diagnostic.	C_1_C5_54	C_1_C6_54 C_1_C7_54	D3_HOS_C2_54
		028x, 0331, 0332, 0333, 0335, 0339, 0342.	Radiology—Therapeutic.	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344	Radioisotope	C_1_C5_56	C_1_C6_56 C_1_C7_56	D3_HOS_C2_56
Computed Tomography (CT) Scan.	CT Scan Charges	035X	Computed Tomography (CT) Scan.	C_1_C5_57	C_1_C6_57 C_1_C7_57	D3_HOS_C2_57
Magnetic Resonance Imaging (MRI).	MRI Charges	061X	Magnetic Resonance Imaging (MRI).	C_1_C5_58	C_1_C6_58 C_1_C7_58	D3_HOS_C2_58
Emergency Room ..	Emergency Room Charges.	045x	Emergency	C_1_C5_91	C_1_C6_91 C_1_C7_91	D3_HOS_C2_91
Blood and Blood Products.	Blood Charges	038x	Whole Blood & Packed Red Blood Cells.	C_1_C5_62	C_1_C6_62 C_1_C7_62	D3_HOS_C2_62
		0819 (for acquisition charges associated with MS–DRG 014 only).				
	Blood Storage/ Processing.	039x	Blood Storing, Processing, & Transfusing.	C_1_C5_63	C_1_C6_63 C_1_C7_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, Columns 6 and 7 and line number) Form CMS–2552–10	Medicare charges from HCRIS (Worksheet D-3, Column and line number) Form CMS–2552–10
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	
			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	
			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	
			FQHC	C_1_C5_89	C_1_C6_89	D3_HOS_C2_89
					C_1_C7_89	

We refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48462) for a discussion on the revenue codes included in the Supplies and Equipment and Implantable Devices CCRs, respectively.

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2013 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 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight.

The FY 2016 cost-based relative weights were then normalized by an adjustment factor of 1.678947 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 19 national average CCRs for FY 2016 are as follows:

Group	CCR
Routine Days	0.480
Intensive Days	0.393
Drugs	0.191
Supplies & Equipment	0.297
Implantable Devices	0.337
Therapy Services	0.332
Laboratory	0.125
Operating Room	0.199
Cardiology	0.118
Cardiac Catheterization	0.124
Radiology	0.159
MRIs	0.085
CT Scans	0.041
Emergency Room	0.183
Blood and Blood Products	0.336
Other Services	0.368
Labor & Delivery	0.404
Inhalation Therapy	0.177
Anesthesia	0.106

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. In the FY 2016 IPPS/LTCH PPS proposed rule, we proposed to use that same case threshold in recalibrating the MS–DRG relative weights for FY 2016. In the FY 2016 IPPS/LTCH PPS proposed rule, we stated that, using data from the FY 2014 MedPAR file, there were 8 MS–DRGs that contain fewer than 10 cases (80 FR 24414). However, we mistakenly included MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C) as a low-volume MS–DRG, which, using data from the December 2014 update of the FY 2014 MedPAR file, had more than 10 cases. For this final rule, using data from the March 2015 update of the FY 2014 MedPAR file, there continue to be 7 MS–DRGs that contain fewer than 10 cases, as reflected in the table below. Under the MS–DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate MS–DRGs for patients aged 0 to 17 years. With the exception of newborns, we previously separated some MS–DRGs based on whether the patient was age 0 to 17 years or age 17 years and older. Other than the age split, cases grouping to these MS–DRGs are identical. The MS–DRGs for patients aged 0 to 17 years generally have very low volumes because children are typically ineligible for Medicare. In the past, we have found that the low volume of cases for the pediatric MS–DRGs could lead to significant year-to-year instability in their relative weights. Although we have always encouraged non-Medicare payers to develop weights applicable to their own patient populations, we have received frequent complaints from providers about the use of the Medicare relative weights in the pediatric population. We believe that eliminating this age split in the MS–DRGs will provide more stable payment for pediatric cases by determining their payment using adult cases that are much higher in total volume. Newborns are unique and require separate MS–DRGs that are not mirrored in the adult population. Therefore, it remains necessary to retain separate MS–DRGs for newborns. All of the low-volume MS–DRGs listed below are for newborns. For FY 2016, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for the following low-volume MS–DRGs, as we proposed, we computed relative weights for the low-volume MS–DRGs by adjusting their final FY 2015 relative weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown below:

Low-volume MS–DRG	MS–DRG Title	Crosswalk to MS–DRG
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2015 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 2015 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	Final FY 2015 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 2015 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS DRGs).
795	Normal Newborn	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

Comment: One commenter stated that the relative weight for MS–DRG 014 (Allogeneic Bone Marrow Transplant) may be understated due to the omission of costs and charges associated with revenue code 0819 which was not included in column 3 of the table of cost report lines and revenue codes on pages 24412 and 24413 of the FY 2016 IPPS/LTCH PPS proposed rule. This commenter also noted that, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24411), CMS removes claims from the relative weight calculation that had an amount in the total charge field that differed by more than $10 from the sum of the routine day charges, intensive care charges, pharmacy charges, special 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 charges, and anesthesia charges. The commenter asserted that if revenue code 0819 is not included in the mapped charges, a difference of greater than $10 would always result on any claim with revenue code 0819, causing the claims with revenue code 0819 to be deleted from the dataset, and the relative weight for MS–DRG 014 to be understated. Another commenter noted that, in response to its question in the past regarding the absence of revenue code 0819 from the cost centers crosswalk table, CMS had indicated that the national Blood and Blood Products CCR is what is used to reduce revenue code 0819 line item charges to costs on inpatient claims. The commenter believed this should be reflected in the table in the final rule so that hospitals are able to use this information to evaluate their internal cost reporting practices. The commenter also mentioned the variability in cost reporting among hospitals related to the Blood and Blood Products cost centers, and noted that some hospitals report

costs and charges related to stem cell transplantation on lines 62 or 63 of the Medicare cost report Form CMS–2552–10, while other hospitals report these costs and charges on line 112, ''Other Organ Acquisition''. The commenter asserted that CMS' use of a cost center group that may have no relation to where and how donor related charges and costs are actually being captured by providers could be one explanation for why the payment rate for MS–DRG 014 does not appropriately account for all donor related costs incurred by providers who perform stem cell transplantations. The commenter expressed hope that, as CMS reviews the use of nonstandard and subscripted cost centers, it also will undertake a review of where and how SCT charges and costs associated with donor related services reported through revenue code 0819 are being accounted for by hospitals in the cost reports. The commenter also was concerned there are no donor source codes in the ICD–10–PCS coding system and urged CMS to address this matter as soon as possible so that provider reporting of donor source codes is not interrupted with the implementation of ICD–10.

Response: Section 90.3.3.A.1 of Chapter 3 of the Medicare Claims Processing Manual states that payment for acquisition services associated with allogeneic stem cell transplants is included in the MS–DRG payment for the allogeneic stem cell transplant when the transplant occurs in the inpatient setting. The MAC will not make separate payment for these acquisition services because hospitals may bill and receive payment only for services provided to a Medicare beneficiary who is the recipient of the stem cell transplant and whose illness is being treated with the stem cell transplant. Unlike the acquisition costs of solid organs for transplant (for example, hearts and kidneys), which are paid on a reasonable cost basis, acquisition costs for allogeneic stem cells are included in the prospective payment. We note that, in each proposed and final IPPS rule, in the description of the calculation of the MS–DRG relative weights, we state that organ acquisition costs are paid on a reasonable cost basis, and therefore, we deduct the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG. (We refer readers to the FY 2016 IPPS/LTCH PPS proposed rule 80 FR 24410 through 24411.) Under section 90.3.3.A.2 of the Medicare Claims Processing Manual, hospitals are to identify stem cell acquisition charges for allogeneic bone marrow/stem cell transplants separately by using revenue code 0819 (Other Organ Acquisition).

Accordingly, charges for allogeneic bone marrow transplants are, in fact, included in the MS–DRG relative weights calculation, in the ''Blood and Blood Products'' CCR. That is, for claims that group into MS–DRG 014, CMS includes the acquisition charges in the blood charges and uses the Blood and Blood Products CCR to adjust those charges to cost. Therefore, contrary to the concern expressed by the first commenter, the relative weight for MS–DRG 014 does reflect costs and charges associated with revenue code 0819, and claims containing revenue code 0819 are not systematically deleted from the dataset. In this final rule and for subsequent rules, we are modifying the crosswalk table for the entry of the Blood and Blood Products cost center group to include revenue code 0819, but we are specifying that only the charges associated with MS–DRG 014 are mapped to the Blood and Blood Products cost center. We are continuing to exclude other 081x revenue codes from the crosswalk table, as these codes are associated with Organ Acquisition, which are otherwise *excluded* from the relative weights calculation because, as explained above, organ acquisition costs are paid on a reasonable cost basis and not under the prospective payment rate.

Regarding the comment which stated that some hospitals report costs and charges related to stem cell transplantation on lines 62 or 63 of the Medicare cost report Form CMS–2552–10, while other hospitals report these costs and charges on line 112, ''Other Organ Acquisition,'' we note that because the charges associated with revenue code 0819 are being mapped by CMS to the Blood and Blood Products cost centers from line 62 (Whole Blood and Packed Red Blood Cells) and line 63 (Blood Storing, Processing, and Transfusions), the appropriate cost centers for hospitals to report the attending costs of allogeneic bone marrow/stem cell transplants are lines 62 and 63 of CMS Form–2552–10. (The cost report instructions for Worksheet A in the Provider Reimbursement Manual (PRM), Part II (Pub. 15–2, Chapter 40, Section 4013, state that hospitals are to include on line 62 ''the direct expenses incurred in obtaining blood directly from donors as well as obtaining whole blood, packed red blood cells, and blood derivatives,'' and ''the processing fee charged by suppliers.'' We also note that line 112, along with the other organ transplant lines 105 through 111, are excluded from the calculation of the CCRs and the IPPS relative weights (and therefore are not listed on the crosswalk table). Consequently, any costs related to charges billed under revenue code 0819 that are reported on line 112 would not be captured in the MS–DRG relative weight calculations.

Regarding the commenter's concern that donor related costs are not being properly reported on the Medicare cost report, and that CMS should undertake a review of where and how donor related services reported through revenue code 0819 are being accounted for by hospitals on the cost reports, we believe this is related to overall inconsistencies in cost reporting, particularly with nonstandard cost centers, which we discuss in section II.E.2. of this final rule. As we state in response to comments received in that section, we appreciate the comments that stakeholders have submitted and will continue to explore ways in which CMS can improve the accuracy of the cost report data and the calculation of CCRs used in the cost estimation process. To the extent possible, we will continue to seek stakeholder input in an effort to limit the impact on hospitals.

Regarding the commenter's concerns that there are no donor source codes under ICD–10–PCS, we note that the donor source is an integral part of all transplant and transfusion codes within ICD–10–PCS. Donor source information is captured in the seventh character qualifiers. For example, the root term ''Transplantation'' provides the following seventh character qualifier values as options to describe donor source: Syngeneic (live related); Allogeneic (live non-related); and Zooplastic (animal). We note that bone marrow transplant procedures are coded to the root operation ''Transfusion'' as stated in the ICD–10–PCS Reference Manual (which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*). The root term ''Transfusion'' provides the seventh character qualifier values of Autologous and Nonautologous as options to describe donor source. For specific questions related to coding for transplants and transfusions, we refer readers to the American Hospital Association (AHA). The AHA Central Office™ is the national clearinghouse for medical coding advice. Coding inquiries may be directed to the following AHA Web site: *http://www.CodingClinicAdvisor.com*.

Comment: One commenter pointed out that the proposed MS–DRG relative weight for MS–DRG 619 (O.R. Procedures for Obesity with MCC) is 2.8830, which is less than the MS–DRG relative weight for this MS–DRG for FY

2015 of 3.2890. The commenter stated that, while this category represents a small percentage of the total bariatric procedures performed on Medicare beneficiaries, patients with conditions described in this MS–DRG are at the greatest risk for readmission and require the greatest support and coordination of postoperative resources to ensure a safe and efficient recovery, and that providers will be unable to provide such support and resources if payment is so drastically reduced. The commenter asked CMS to reconsider the reduction, and consider an increase of 1.1 percent in the relative weight for MS–DRG 619 in keeping with Hospital IQR Program and meaningful electronic health record (EHR) user incentives. The commenter asked that, for hospitals not participating in the Hospital IQR Program or the EHR Incentive Program, CMS keep the relative weight for MS–DRG 619 neutral.

Response: We note that, while the proposed FY 2016 relative weight for MS–DRG 619 was 2.8830, the final FY 2016 relative weight for MS–DRG 619 is 2.9418 (as reflected in Table 5 associated with this final rule and available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html*). While we are sympathetic to the commenter's concerns, we note that the reduction in the relative weight from FY 2015 to FY 2016 is a function of the relative weight calculation, as described in section II.H. of the FY 2016 IPPS/LTCH PPS proposed rule and this final rule, which is comprised of hospitals' billed charges for MS–DRG 619 and the costs reported on hospitals' cost reports. The reduction in the relative weight may be attributed to the change in the number of cases and average charges for MS–DRG 619 used to develop the relative weight for FY 2015 and the final FY 2016 relative weight. Specifically, we observed that FY 2015 cases were 896, and FY 2016 cases are 1,037, while FY 2015 average charges were $90,806, and FY 2016 average charges are $84,592.

We are finalizing the methodology for recalibration of the MS–DRG relative weights specified in this final rule for FY 2016 as proposed.

4. Discussion and Acknowledgement of Public Comments Received on Expanding the Bundled Payments for Care Improvement (BPCI) Initiative

a. Background

Since 2011, CMS has been working to develop and test models of bundling Medicare payments under the authority of section 1115A of the Act. Through these models, CMS plans to evaluate whether bundled payments result in higher quality and more coordinated care at a lower cost to Medicare. CMS is currently testing the Bundled Payments for Care Improvement (BPCI) initiative. Under this initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care.

The BPCI initiative is comprised of four related payment models, which link payments for multiple services that Medicare beneficiaries receive during an episode of care into a bundled payment. Episodes of care under the BPCI initiative begin with either (1) an inpatient hospital stay or (2) postacute care services following a qualifying inpatient hospital stay. More information on the four models under the BPCI initiative can be found on the CMS Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/bundled-payments/*.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24414 through 24418), we presented a discussion of the models in the BPCI initiative and solicited public comments regarding policy and operational issues related to a potential expansion of the BPCI initiative in the future. Section 1115A(c) of the Act, as added by section 3021 of the Affordable Care Act, provides the Secretary with the authority to expand through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act, such as the BPCI initiative (including implementation on a nationwide basis), if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce Medicare spending without reducing the quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net Medicare program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of Medicare benefits. The decision of whether or not to expand will be made by the Secretary in coordination with CMS and the Office of the Chief Actuary based on whether findings about the initiative meet the statutory criteria for expansion under section 1115A(c) of the Act. Given that further evaluation of the BPCI initiative is needed to determine its impact on both Medicare cost and quality of care, we did not propose an expansion of any models within the initiative or any policy changes associated with it in the FY 2016 IPPS/LTCH PPS proposed rule.

Consistent with our continuing commitment to engaging stakeholders in CMS' work, we sought public comments on a variety of issues to broaden and deepen our understanding of the important issues and challenges regarding bundled payments in the current health care marketplace. Among other subject-matter areas, we sought public comments on the scope of any expansion, episode definitions, bundled payment amounts, data needs, and the use of health information technology. In response to our solicitation, we received over 75 timely and informative public comments suggesting matters to consider in a potential future expansion of the BPCI initiative, including the evaluation of the BPCI models, further testing of the BPCI initiative, target pricing methodologies, data collection and reporting, quality measures, episode definitions, payment methodologies, and precedence rules. We appreciate the commenters' views and recommendations. We will consider the public comments we received if the BPCI initiative is expanded in the future through rulemaking.

I. Add-On Payments for New Services and Technologies for FY 2016

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, 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 by FDA and has been on the market for more than 2 to 3 years. In the FY 2006 IPPS final rule (70 FR 47351) and the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 and 43814), we explained our policy regarding substantial similarity in detail.

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 the discharge involving the new medical services or technologies 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. We update the thresholds in Table 10 of each final rule that apply for the upcoming fiscal year. Table 10 that was released with the FY 2015 IPPS/LTCH PPS final rule contains the final thresholds that we used to evaluate applications for new medical service and new technology add-on payments for FY 2016. We refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2015–IPPS-Final-Rule-Home-Page-Items/FY2015-Final-Rule-Tables.html* to download and view Table 10.

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 and new 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 new 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 each 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 claims-payment contractors (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 Web site, in a user-friendly format. This guide was published in 2010 and is available on the CMS Web site at: *http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.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 2017 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 Web site at: *http://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 2017, the CMS Web site also will post the tracking forms completed by each applicant.

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 2016 prior to publication of the FY 2016 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 21, 2014 (79 FR 69490), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 3, 2015. In the announcement notice for the meeting, we stated that the opinions and alternatives 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 2016 new medical service and technology add-on payment applications before the publication of the FY 2016 IPPS/LTCH PPS proposed rule.

Approximately 95 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=dn-R5KGQu-M*. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of January 19, 2015, in our evaluation of the new technology add-on payment applications for FY 2016 in the proposed rule.

In response to the published notice and the New Technology Town Hall meeting, we received written comments regarding the applications for FY 2016 new technology add-on payments. We summarized these comments in the preamble of the proposed rule or, if applicable, indicated that there were no comments received, at the end of each discussion of the individual applications in the proposed rule. We are not reprinting those summations in this final rule and refer readers to the FY 2016 IPPS/LTCH PPS proposed rule for this discussion.

We also received public comments in response to the proposed rule relating to topics such as marginal cost factors for new technology add-on payments, mapping new technologies to the appropriate MS–DRG, additional criteria for substantial clinical improvement, and changing the newness criterion. Because we did not request public comments nor propose to make any changes to any of the issues above, we are not summarizing these public comments nor responding to them in this final rule.

Comment: One commenter stated that it is not appropriate for CMS to continue to add requirements or to impose standards that exceed realistic requirements for clinical trials. The commenter cited the WATCHMAN® System as an example where CMS suggested that substantial clinical improvement should be based on a superiority trial rather than the noninferiority trial that was used.

Response: We received a similar public comment last year and responded to it in the FY 2015 IPPS/LTCH PPS final rule. We refer the readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49925 through 49926) for a complete response to this issue.

3. Implementation of ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies for FY 2016

As discussed in section II.G.1.a. of the preamble of this final rule, HIPAA covered entities are required, as of October 1, 2015, to use the ICD–10 coding system (ICD–10–PCS codes for procedures and ICD–10–CM codes for diagnosis), instead of the ICD–9–CM coding system, to report diagnoses and procedures for Medicare hospital inpatient services provided to Medicare beneficiaries as classified under the MS–DRG system and paid for under the IPPS. HIPAA covered entities must continue to use ICD–9–CM codes and coding guidelines through September 30, 2015. We refer readers to section II.G.1.a. of the preamble of this final rule for a complete discussion of the adoption of the ICD–10 coding system.

As part of the transition to the ICD–10–CM/PCS coding system, at the September 23–24, 2014 ICD–10 Coordination and Maintenance Committee meeting, CMS received a request to create a new section within the ICD–10–PCS to capture new medical services and technologies that might not appropriately align with the current structure of the ICD–10–PCS codes. Examples of these types of new medical services and technologies included drugs, biologicals, and newer medical devices being tested in clinical trials that are not currently captured within the ICD–9–CM or the ICD–10–PCS. The requestor indicated that there may be a need to identify and report these technologies and inpatient services for purposes of approving new technology add-on payment applications and initiating subsequent new technology add-on payments based on approval or tracking and analyzing the use of these new technologies and services. Although several commenters have opposed including these types of technologies and services within the current structure of the ICD–10–PCS codes during past ICD–10 Coordination and Maintenance Committee meetings, as well as in public comments, CMS has evaluated these suggestions and considered them to be valid. As a result, CMS has created a new component within the ICD–10–PCS codes, labeled Section ''X'' codes, to identify and describe these new technologies and services. The new Section ''X'' codes identify new medical services and technologies that are not usually captured by coders, or that do not usually have the desired specificity within the current ICD–10–PCS structure required to capture the use of these new services and technologies. As mentioned earlier, examples of these types of services and technologies include specific drugs, biologicals, and newer medical devices being tested in clinical trials. The new Section ''X'' codes within the ICD–10–PCS structure will be implemented on October 1, 2015, and will be used to identify new technologies and medical services approved under the new technology add-on payment policy for payment purposes beginning October 1, 2015. The Section ''X'' codes also will be used to identify procedures or services that are not commonly captured within the definitions and descriptions included in most coding systems or procedures or services that require definitions and descriptions that contain greater detail or specificity, which may be needed for a variety of health care data needs. An overview of Section ''X'' codes was provided at the March 18–19, 2015 ICD–10 Coordination and Maintenance Committee meeting. We also have posted an article on the CMS Web site that explains the creation and use of ICD–10–PCS Section ''X'' codes. This article can be found on the CMS 2016 ICD–10–PCS and GEMs Web site at *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*. Further information regarding the new Section ''X'' codes and their use within the ICD–10–PCS can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html* through the ''CMS Coordination and Maintenance Committee Meeting'' link.

In addition, on June 18, 2015, CMS held a National ICD–10 Teleconference (Preparing for Implementation and New ICD–10–PCS Section ''X'' MLN Connects National Provider Call) to explain the Section ''X'' codes under the ICD–10. The agenda, slides, and audio from this teleconference are posted on the CMS Web site at: *http://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2015-06-18-ICD10.html?DLPage=1&DLSort=0&DLSortDir=descending*.

As stated earlier, the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which will be used beginning 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. The FY 2016 ICD–10–PCS, which includes the new Section ''X'' codes, was posted in June 2015 via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*. We also posted the FY 2016 ICD–10–PCS Guidelines on this CMS Web site that also includes guidelines for ICD–10–PCS ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

Comment: Several commenters supported the creation of the new ICD–10–PCS Section ''X'' codes as a means to more specifically identify new technologies or more precise information about certain services. The commenters recognized the challenges of maintaining a partial code freeze while at the same time finding a way to capture new procedures. One commenter who supported the creation of the new Section ''X'' codes to identify new medical services and technologies stated that it was important to have a more robust coding system that will allow for recognition of more technologies, procedures, and variations in patients' conditions.

Another commenter recognized the need to conserve code values within the regular ICD–10–PCS sections, as well as the exponential effect that adding a new value has on the large number of codes, and noted the importance of using Section ''X'' codes specifically for certain types of new technologies. The commenter stated that Section ''X'' codes are especially important to identify drugs and intraoperative supplies related to MS–DRG new technology add-on payments.

Response: We appreciate the commenters' support.

Comment: Several commenters expressed concern that payers may mistakenly consider ICD–10–PCS Section ''X'' codes as interchangeable with CPT Category III codes. The commenters stated that, although CPT Category III codes also represent emerging technologies, the technologies lack substantive support in professional literature, and the codes used for these technologies often describe noncovered procedures that are experimental or investigational. In contrast, the commenter recognized that ICD–10–PCS Section ''X'' codes describe new technologies or services that frequently are FDA approved. However, the

commenters asked that CMS clarify that ICD–10–PCS Section ''X'' codes will not be used to specifically identify experimental or unproven procedures.

Response: Section ''X'' codes were created to more specifically identify new technologies, procedures that have historically not been captured through ICD–9–CM codes, or to more precisely describe information on a specific procedure or technology than is found with the other sections of ICD–10–PCS. Section ''X'' codes were not created, nor intended to be used, to identify experimental or investigational procedures.

Comment: Several commenters expressed concerns about the decision to create new codes during the partial code freeze, in particular the creation of the ICD–10–PCS Section ''X'' during the partial code freeze. The commenters believed that it would be more appropriate to delay the implementation of this section of the ICD–10–PCS and the use of Section ''X'' codes until after the ICD–10 coding system is implemented and the partial code freeze ends. The commenters also requested clarifications on how the new Section ''X'' codes would be used.

Response: We acknowledge that it has been a challenge for CMS to implement the ICD–10–PCS/CM coding system, particularly in light of the partial code freeze and several delays of the implementation of ICD–10. However, the partial code freeze has allowed sufficient time and the ability to capture new technologies or new medical services under the new coding system. Many participants at the ICD–10 Coordination and Maintenance Committee have voiced opposition to the creation of any new codes during the partial code freeze. Other participants have actively encouraged the creation of more code updates beyond those that capture new technologies or new medical services. We have given consideration to all of the public comments presented at the ICD–10 Coordination and Maintenance Committee meetings and have attempted to make updates to the ICD–10–CM/PCS in a manner that is most appropriate and results in less burden on the majority of users. Any updates to ICD–10–CM/PCS, including updates to the Section ''X'' codes, will be presented at future ICD–10 Coordination and Maintenance Committee meetings for public comments. For those individuals who are interested in participating in future ICD–10 Coordination and Maintenance Committee meetings, information on the Committee can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html*. We encourage public participation at these meetings either in person, by conference lines, or by the livestream provided by CMS. As discussed earlier, CMS has posted the FY 2016 ICD–10–PCS guidelines, which include guidelines on the use of Section ''X'' codes and an article explaining why ICD–10–PCS Section ''X'' codes were created and how to use them on the CMS Web site. We believe that this detailed information will assist coders in using the new Section ''X'' codes.

4. FY 2016 Status of Technologies Approved for FY 2015 Add-On Payments

a. Glucarpidase (Voraxaze®)

BTG International, Inc. submitted an application for new technology add-on payments for Glucarpidase (Voraxaze®) for FY 2013. Glucarpidase is used in the treatment of patients who have been diagnosed with toxic methotrexate (MTX) concentrations as of result of renal impairment. The administration of Glucarpidase causes a rapid and sustained reduction of toxic MTX concentrations.

Voraxaze® was approved by the FDA on January 17, 2012. Beginning in 1993, certain patients could obtain expanded access for treatment use to Voraxaze® as an investigational drug. Since 2007, the applicant has been authorized to recover the costs of making Voraxaze® available through its expanded access program. We describe expanded access for treatment use of investigational drugs and authorization to recover certain costs of investigational drugs in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53346 through 53350). Voraxaze® was available on the market in the United States as a commercial product to the larger population as of April 30, 2012. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27936 through 27939), we expressed concerns about whether Voraxaze® could be considered new for FY 2013. After consideration of all of the public comments received, in the FY 2013 IPPS/LTCH PPS final rule, we stated that we considered Voraxaze® to be ''new'' as of April 30, 2012, which is the date of U.S. market availability.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for Voraxaze® and consideration of the public comments we received in response to the FY 2013 IPPS/LTCH PPS proposed rule, we approved Voraxaze® for new technology add-on payments for FY 2013. Cases of Voraxaze® are identified with ICD–9–CM procedure code 00.95 (Injection or infusion of glucarpidase). As stated in the FY 2015 IPPS/LTCH PPS final rule correction notice (79 FR 59679), the cost of Voraxaze® is $23,625 per vial. The applicant stated that an average of four vials is used per Medicare beneficiary. Therefore, the average cost per case for Voraxaze® is $94,500 ($23,625 × 4). 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 Voraxaze® is $47,250 per case.

As stated above, the new technology add-on payment regulations provide that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (§ 412.87(b)(2)). 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 add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362).

With regard to the newness criterion for Voraxaze®, we considered the beginning of the newness period to commence when Voraxaze® was first made available on the U.S. market on April 30, 2012. Because the 3-year anniversary date for Voraxaze® occurred in the latter half of FY 2015 (April 30, 2015), in the FY 2015 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2015 (79 FR 49918). However, for FY 2016, the 3-year anniversary date of the product's entry on the U.S. market (April 30, 2015) occurred prior to the beginning of FY 2016. Therefore, we proposed to discontinue new technology add-on payments for Voraxaze® for FY 2016. We invited public comments on this proposal.

Comment: One commenter supported CMS' proposal to discontinue new technology add-on payments for Voraxaze® for FY 2016.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are discontinuing new technology add-on payments for Voraxaze® for FY 2016. The 3-year anniversary date of the

product's entry onto the U.S. market occurred prior to the beginning of FY 2016 and, therefore, the technology will no longer be eligible for new technology add-on payments because the technology will no longer meet the ''newness'' criterion.

b. Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft

Cook® Medical submitted an application for new technology add-on payments for the Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft (Zenith® F. Graft) for FY 2013. The applicant stated that the current treatment for patients who have had an AAA is an endovascular graft. The applicant explained that the Zenith® F. Graft is an implantable device designed to treat patients who have an AAA and who are anatomically unsuitable for treatment with currently approved AAA endovascular grafts because of the length of the infrarenal aortic neck. The applicant noted that, currently, an AAA is treated through an open surgical repair or medical management for those patients not eligible for currently approved AAA endovascular grafts.

With respect to newness, the applicant stated that FDA approval for the use of the Zenith® F. Graft was granted on April 4, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53360 through 53365), we stated that because the Zenith® F. Graft was approved by the FDA on April 4, 2012, we believed that the Zenith® F. Graft met the newness criterion as of that date.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the Zenith® F. Graft and consideration of the public comments we received in response to the FY 2013 IPPS/LTCH PPS proposed rule, we approved the Zenith® F. Graft for new technology add-on payments for FY 2013. Cases involving the Zenith® F. Graft that are eligible for new technology add-on payments currently are identified by ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta). In the application, the applicant provided a breakdown of the costs of the Zenith® F. Graft. The total cost of the Zenith® F. Graft utilizing bare metal (renal) alignment stents was $17,264. Of the $17,264 in costs for the Zenith® F. Graft, $921 is for components that are used in a standard Zenith AAA Endovascular Graft procedure. Because the costs for these components are already reflected within the MS–DRGs (and are no longer ''new''), in the FY 2013 IPPS/LTCH PPS final rule, we stated that we did not believe it is appropriate to include these costs in our calculation of the maximum cost to determine the maximum add-on payment for the Zenith® F. Graft. Therefore, the total maximum cost for the Zenith® F. Graft is $16,343 ($17,264 − $921). 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 add-on payment for a case involving the Zenith® F. Graft is $8,171.50.

With regard to the newness criterion for the Zenith® F. Graft, we considered the beginning of the newness period to commence when the Zenith® F. Graft was approved by the FDA on April 4, 2012. Because the 3-year anniversary date of the entry of the Zenith® F. Graft on the U.S. market occurred in the second half of FY 2015 (April 4, 2015), in the FY 2015 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2015 (79 FR 49922). However, for FY 2016, the 3-year anniversary date of the product's entry on the U.S. market (April 4, 2015) occurred prior to the beginning of FY 2016. Therefore, we proposed to discontinue new technology add-on payments for the Zenith® F. Graft for FY 2016. We invited public comments on this proposal.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are discontinuing new technology add-on payments for the Zenith® F. Graft technology for FY 2016. The 3-year anniversary of the product's entry onto the U.S. market occurred prior to the beginning of FY 2016 and, therefore, the technology is not eligible for new technology add-on payments for FY 2016 because the technology will no longer meet ''newness'' criterion.

c. Kcentra™

CSL Behring submitted an application for new technology add-on payments for Kcentra™ for FY 2014. Kcentra™ is a replacement therapy for fresh frozen plasma (FFP) for patients with an acquired coagulation factor deficiency due to warfarin and who are experiencing a severe bleed. Kcentra™ contains the Vitamin K dependent coagulation factors II, VII, IX and X, together known as the prothrombin complex, and antithrombotic proteins C and S. Factor IX is the lead factor for the potency of the preparation. The product is a heat-treated, non-activated, virus filtered and lyophilized plasma protein concentrate made from pooled human plasma. Kcentra™ is available as a lyophilized powder that needs to be reconstituted with sterile water prior to administration via intravenous infusion. The product is dosed based on Factor IX units. Concurrent Vitamin K treatment is recommended to maintain blood clotting factor levels once the effects of Kcentra™ have diminished.

Kcentra™ was approved by the FDA on April 29, 2013. In the FY 2014 IPPS/LTCH PPS final rule, we finalized new ICD–9–CM procedure code 00.96 (Infusion of 4-Factor Prothrombrin Complex Concentrate) which uniquely identifies Kcentra™.

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27538), we noted that we were concerned that Kcentra™ may be substantially similar to FFP and/or Vitamin K therapy. In the FY 2014 IPPS/LTCH PPS final rule, in response to comments submitted by the manufacturer, we stated that we agree that Kcentra™ may be used in a patient population that is experiencing an acquired coagulation factor deficiency due to Warfarin and who are experiencing a severe bleed currently but are ineligible for FFP, particularly for use by IgA deficient patients and other patient populations that have no other treatment option to resolve severe bleeding in the context of an acquired Vitamin K deficiency. In addition, FFP is limited because it requires special storage conditions while Kcentra™ is stable for up to 36 months at room temperature thus allowing hospitals that otherwise would not have access to FFP (for example, small rural hospitals as discussed by the applicant in its comments) to keep a supply of Kcentra™ and treat patients who would possibly have no access to FFP. We noted that FFP is considered perishable and can be scarce by nature (due to production and other market limitations) thus making some hospitals unable to store FFP, which limits access to certain patient populations in certain locations. Therefore, we stated that we believe that Kcentra™ provides a therapeutic option for a new patient population and is not substantially similar to FFP. Also, we gave credence to the information presented by the manufacturer that Kcentra™ provides a simple and rapid repletion relative to FFP and reduces the risk of a transfusion reaction relative to FFP because it does not contain ABO antibodies and does not require ABO typing. As a result, we concluded that Kcentra™ is not substantially similar to FFP, and that it meets the newness criterion.

After evaluation of the newness, cost, and substantial clinical improvement criteria for new technology add-on payments for Kcentra™ and consideration of the public comments we received in response to the FY 2014 IPPS/LTCH PPS proposed rule, we approved Kcentra™ for new technology add-on payments for FY 2014 (78 FR 50575 through 50580). Cases involving Kcentra™ that are eligible for new technology add-on payments currently are identified by ICD–9–CM procedure code 00.96. In the application, the applicant estimated that the average Medicare beneficiary would require an average dosage of 2500 International Units (IU). Vials contain 500 IU at a cost of $635 per vial. Therefore, cases of Kcentra™ would incur an average cost per case of $3,175 ($635 × 5). 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 add-on payment for a case of Kcentra™ was $1,587.50 for FY 2014.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50579), we stated that new technology add-on payments for Kcentra™ would not be available with respect to discharges for which the hospital received an add-on payment for a blood clotting factor administered to a Medicare beneficiary with hemophilia who is a hospital inpatient. Under section 1886(d)(1)(A)(iii) of the Act, the national adjusted DRG prospective payment rate is the amount of the payment with respect to the operating costs of inpatient hospital services (as defined in subsection (a)(4)) for discharges on or after April 1, 1988. Section 1886(a)(4) of the Act excludes from the term ''operating costs of inpatient hospital services'' the costs with respect to administering blood clotting factors to individuals with hemophilia. The costs of administering a blood clotting factor to a Medicare beneficiary who has hemophilia and is a hospital inpatient are paid separately from the IPPS. (For information on how the blood clotting factor add-on payment is made, we refer readers to Section 20.7.3, Chapter 3, of the Medicare Claims Processing Manual, which can be downloaded from the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.*) In addition, we stated that if Kcentra™ is approved by the FDA as a blood clotting factor, we believed that it may be eligible for blood clotting factor add-on payments when administered to Medicare beneficiaries with hemophilia. We make an add-on payment for Kcentra™ for such discharges in accordance with our policy for payment of a blood clotting factor, and the costs would be excluded from the operating costs of inpatient hospital services as set forth in section 1886(a)(4) of the Act.

Section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under this subsection beginning with discharges on or after October 1, 2001. We believe that it is reasonable to interpret this requirement to mean that the payment mechanism established by the Secretary recognizes only costs for those items that would otherwise be paid based on the prospective payment system (that is, ''the payment system established under this subsection''). As noted above, under section 1886(d)(1)(A)(iii) of the Act, the national adjusted DRG prospective payment rate is the amount of payment for the operating costs of inpatient hospital services, as defined in section 1886(a)(4) of the Act, for discharges on or after April 1, 1988. We understand this to mean that a new medical service or technology must be an operating cost of inpatient hospital services paid based on the prospective payment system, and not excluded from such costs, in order to be eligible for the new technology add-on payment. We pointed out that new technology add-on payments are based on the operating costs per case relative to the prospective payment rate as described in § 412.88. Therefore, we believe that new technology add-on payments are appropriate only when the new technology is an operating cost of inpatient hospital services and are not appropriate when the new technology is excluded from such costs.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50579), we stated that we believe that hospitals may only receive new technology add-on payments for discharges where Kcentra™ is an operating cost of inpatient hospital services. In other words, a hospital would not be eligible to receive the new technology add-on payment when it is administering Kcentra™ in treating a Medicare beneficiary who has hemophilia. In those instances, Kcentra™ is specifically excluded from the operating costs of inpatient hospital services in accordance with section 1886(a)(4) of the Act and paid separately from the IPPS. However, when a hospital administers Kcentra™ to a Medicare beneficiary who does not have hemophilia, the hospital would be eligible for a new technology add-on payment because Kcentra™ would not be excluded from the operating costs of inpatient hospital services. Therefore, discharges where the hospital receives a blood clotting factor add-on payment are not eligible for a new technology add-on payment for the blood clotting factor. We refer readers to Section 20.7.3, Chapter 3, of the Medicare Claims Processing Manual for a complete discussion on when a blood clotting factor add-on payment is made. The manual can be downloaded from the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.*

With regard to the newness criterion for Kcentra™, we considered the beginning of the newness period to commence when Kcentra™ was approved by the FDA on April 29, 2013. Because the 3-year anniversary date of the entry of Kcentra™ on the U.S. market will occur in the second half of FY 2016 (April 29, 2016), we proposed to continue new technology add-on payments for this technology for FY 2016.

Because we are adopting the ICD–10 coding system effective October 1, 2015, for FY 2016, we proposed to identify and make new technology add-on payments for cases involving Kcentra™ with ICD 10 PCS procedure code 30283B1 (Transfusion of nonautologous 4-factor prothrombin complex concentrate into vein, percutaneous approach). We stated that the maximum new technology add-on payment for a case involving the Kcentra™ technology would remain at $1,587.50 for FY 2016.

We invited public comments on these proposals.

Comment: One commenter supported CMS' proposal to continue new technology add-on payments for Kcentra™ for FY 2016.

Response: We appreciate the commenter's support.

We did not receive any public comments on the coding and payment for Kcentra™ for FY 2016.

After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for the Kcentra™ technology for FY 2016. Because we are adopting the ICD–10 coding system effective October 1, 2015, for FY 2016, as we proposed, we will identify and make new technology add-on payments for cases involving Kcentra™ with the presence of ICD–10–PCS procedure code 30283B1 (Transfusion of nonautologous 4-factor prothrombin complex concentrate into vein, percutaneous approach). New technology add-on payments for

Kcentra™ will not be available with respect to discharges for which the hospital received an add-on payment for a blood clotting factor administered to a Medicare beneficiary with hemophilia who is a hospital inpatient. For information on how the blood clotting factor add-on payment is made (including a list of ICD–10 diagnosis codes that would negate the eligibility of a case for new technology add-on payments, if reported in combination with the ICD–10 procedure code used to identify cases involving the Kcentra™ technology), we refer readers to Section 20.7.3, Chapter 3, of the Medicare Claims Processing Manual, which is available via the Internet on the CMS Web site at: *http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*. The maximum new technology add-on payment for a case involving the Kcentra™ technology will remain at $1,587.50 for FY 2016.

d. Argus® II Retinal Prosthesis System

Second Sight Medical Products, Inc. submitted an application for new technology add-on payments for the Argus® II Retinal Prosthesis System (Argus® II System) for FY 2014. The Argus® II System is an active implantable medical device that is intended to provide electrical stimulation of the retina to induce visual perception in patients who are profoundly blind due to retinitis pigmentosa (RP). These patients have bare or no light perception in both eyes. The system employs electrical signals to bypass dead photo-receptor cells and stimulate the overlying neurons according to a real-time video signal that is wirelessly transmitted from an externally worn video camera. The Argus® II implant is intended to be implanted in a single eye, typically the worse-seeing eye. Currently, bilateral implants are not intended for this technology. According to the applicant, the surgical implant procedure takes approximately 4 hours and is performed under general anesthesia.

The Argus® II System consists of three primary components: (1) An implant which is an epiretinal prosthesis that is fully implanted on and in the eye (that is, there are no percutaneous leads); (2) external components worn by the user; and (3) a ''fitting'' system for the clinician that is periodically used to perform diagnostic tests with the system and to custom-program the external unit for use by the patient. We describe these components more fully below.

- *Implant:* The retinal prosthesis implant is responsible for receiving information from the external components of the system and electrically stimulating the retina to induce visual perception. The retinal implant consists of: (a) A receiving coil for receiving information and power from the external components of the Argus® II System; (b) electronics to drive stimulation of the electrodes; and (c) an electrode array. The receiving coil and electronics are secured to the outside of the eye using a standard scleral band and sutures, while the electrode array is secured to the surface of the retina inside the eye by a retinal tack. A cable, which passes through the eye wall, connects the electronics to the electrode array. A pericardial graft is placed over the extra-ocular portion on the outside of the eye.
- *External Components:* The implant receives power and data commands wirelessly from an external unit of components, which include the Argus II Glasses and Video Processing Unit (VPU). A small lightweight video camera and transmitting coil are mounted on the glasses. The telemetry coils and radio-frequency system are mounted on the temple arm of the glasses for transmitting data from the VPU to the implant. The glasses are connected to the VPU by a cable. This VPU is worn by the patient, typically on a belt or a strap, and is used to process the images from the video camera and convert the images into electrical stimulation commands, which are transmitted wirelessly to the implant.
- *''Fitting System'':* To be able to use the Argus® II System, a patient's VPU needs to be custom-programmed. This process, which the applicant called ''fitting'', occurs in the hospital/clinic shortly after the implant surgery and then periodically thereafter as needed. The clinician/physician also uses the ''Fitting System'' to run diagnostic tests (for example, to obtain electrode and impedance waveform measurements or to check the radio-frequency link between the implant and external unit). This ''Fitting System'' can also be connected to a ''Psychophysical Test System'' to evaluate patients' performance with the Argus® II System on an ongoing basis.

These three components work together to stimulate the retina and allow a patient to perceive phosphenes (spots of light), which they then need to learn to interpret. While using the Argus® II System, the video camera on the patient-worn glasses captures a video image. The video camera signal is sent to the VPU, which processes the video camera image and transforms it into electrical stimulation patterns. The electrical stimulation data are then sent to a transmitter coil mounted on the glasses. The transmitter coil sends both data and power via radio-frequency (RF) telemetry to the implanted retinal prosthesis. The implant receives the RF commands and delivers stimulation to the retina via an array of electrodes that is secured to the retina with a retinal tack.

In patients with RP, the photoreceptor cells in the retina, which normally transduce incoming light into an electro-chemical signal, have lost most of their function. The stimulation pulses delivered to the retina via the electrode array of the Argus® II System are intended to mimic the function of these degenerated photoreceptors cells. These pulses induce cellular responses in the remaining, viable retinal nerve cells that travel through the optic nerve to the visual cortex where they are perceived as phosphenes (spots of light). Patients learn to interpret the visual patterns produced by these phosphenes.

With respect to the newness criterion, according to the applicant, the FDA designated the Argus® II System a Humanitarian Use Device in May 2009 (HUD designation #09–0216). The applicant submitted a Humanitarian Device Exemption (HDE) application (#H110002) to the FDA in May 2011 to obtain market approval for the Argus® II System. The HDE was referred to the Ophthalmic Devices Panel of the FDA's Medical Devices Advisory Committee for review and recommendation. At the Panel's meeting held on September 28, 2012, the Panel voted 19 to 0 that the probable benefits of the Argus® II System outweigh the risks of the system for the proposed indication for use. The applicant received the HDE approval from the FDA on February 14, 2013. However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49924 through 49925), we discussed comments we had received informing CMS that the Argus® II System was not available on the U.S. market until December 20, 2013. The applicant explained that, as part of the lengthy approval process, it was required to submit a request to the Federal Communications Commission (FCC) for a waiver of section 15.209(a) of the FCC rules that would allow the applicant to apply for FCC authorization to utilize this specific RF band. The FCC approved the applicant's waiver request on November 30, 2011. After receiving the FCC waiver of the section 15.209(a) rules, the applicant requested and obtained a required Grant of Equipment Authorization to utilize the specific RF band, which the FCC issued on December 20, 2013. Therefore, the applicant stated that the date the Argus® II System first became available for commercial sale in the United States

was December 20, 2013. We agreed with the applicant that, due to the delay, the date of newness for the Argus® II System was December 20, 2013, instead of February 14, 2013.

Currently there are no other approved treatments for patients diagnosed with severe to profound RP. The Argus® II System has an IDE number of G050001 and is a Class III device. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50580 through 50583), we finalized new ICD–9–CM procedure code 14.81 (Implantation of epiretinal visual prosthesis), which uniquely identifies the Argus® II System. The other two codes finalized by CMS are for removal, revision, or replacement of the device.

After evaluation of the new technology add-on payment application and consideration of public comments received, we concluded that the Argus® II System met all of the new technology add-on payment policy criteria. Therefore, we approved the Argus® II System for new technology add-on payments in FY 2014 (78 FR 50580 through 50583). Cases involving the Argus® II System that are eligible for new technology add-on payments currently are identified by ICD–9–CM procedure code 14.81. We note that section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act, which makes no mention of any add-on payments for a new medical service or technology. Therefore, it is not appropriate to include capital costs in the add-on payments for a new medical service or technology. In the application, the applicant provided a breakdown of the costs of the Argus® II System. The total operating cost of the Argus® II System is $144,057.50. 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 add-on payment for a case involving the Argus® II System for FY 2014 was $72,028.75.

With regard to the newness criterion for the Argus® II System, we considered the beginning of the newness period to commence when the Argus® II System became available on the U.S. market on December 20, 2013. Because the 3-year anniversary date of the entry of the Argus® II System on the U.S. market will occur in the first half of FY 2017 (December 23, 2016), we proposed to continue new technology add-on payments for this technology for FY 2016.

Because we are adopting the ICD–10 coding system beginning October 1, 2015, we proposed to identify and make new technology add-on payments for cases involving the Argus® II System when one of the following ICD–10–PCS procedure codes is reported: 08H005Z (Insertion of epiretinal visual prosthesis into right eye, open approach); or 08H105Z (Insertion of epiretinal visual prosthesis into left eye, open approach). We stated that the maximum new technology add-on payment for a case involving the Argus® II System would remain at $72,028.75 for FY 2016.

We invited public comments on our proposals.

We did not receive any public comments on our proposal to continue new technology add-on payments for the Argus® II System for FY 2016 or on the coding and payment of this technology. Therefore, we are finalizing our proposal to continue new technology add-on payments for the Argus® II System for FY 2016. Because we are adopting the ICD–10 coding system beginning October 1, 2015, we will identify and make new technology add-on payments for cases involving the Argus® II System when ICD–10–PCS procedure code 08H005Z or 08H105Z is reported. The maximum new technology add-on payment for a case involving the Argus® II System remains at $72,028.75 for FY 2016.

e. Zilver® PTX® Drug Eluting Peripheral Stent

Cook® Medical submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Peripheral Stent (Zilver® PTX®) for FY 2014. The Zilver® PTX® is intended for use in the treatment of peripheral artery disease (PAD) of the above–the-knee femoropopliteal arteries (superficial femoral arteries). According to the applicant, the stent is percutaneously inserted into the artery(s), usually by accessing the common femoral artery in the groin. The applicant stated that an introducer catheter is inserted over the wire guide and into the target vessel where the lesion will first be treated with an angioplasty balloon to prepare the vessel for stenting. The applicant indicated that the stent is self-expanding, made of nitinol (nickel titanium), and is coated with the drug Paclitaxel. Paclitaxel is a drug approved for use as an anticancer agent and for use with coronary stents to reduce the risk of renarrowing of the coronary arteries after stenting procedures.

The applicant received FDA approval on November 15, 2012, for the Zilver® PTX®. The applicant maintains that the Zilver® PTX® is the first drug-eluting stent used for superficial femoral arteries. The technology is currently described by ICD–9–CM procedure code 00.60 (Insertion of drug-eluting stent(s) of the superficial femoral artery).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50583 through 50585), after evaluation of the new technology add-on payment application and consideration of the public comments received, we approved the Zilver® PTX® for new technology add-on payments in FY 2014. Cases involving the Zilver® PTX® that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 00.60. As explained in the FY 2014 IPPS/LTCH PPS final rule, to determine the amount of Zilver® PTX® stents per case, instead of using the amount of stents used per case based on the ICD–9–CM codes, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study. The applicant stated in its application that the anticipated cost per stent is approximately $1,795. Therefore, cases of the Zilver® PTX® would incur an average cost per case of $3,410.50 ($1,795 × 1.9). 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 add-on payment for a case of the Zilver® PTX® was $1,705.25 for FY 2014.

With regard to the newness criterion for the Zilver® PTX®, we considered the beginning of the newness period to commence when the Zilver® PTX® was approved by the FDA on November 15, 2012. Because the 3-year anniversary date of the entry of the Zilver® PTX® on the U.S. market occurred after FY 2015 (November 15, 2015), in the FY 2015 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2015 (79 FR 49925). However, for FY 2016, the 3-year anniversary date of the product's entry on the U.S. market (November 15, 2015) occurs in the first half of FY 2016. Therefore, we proposed to discontinue new technology add-on payments for the Zilver® PTX® for FY 2016. We invited public comments on this proposal.

Comment: One commenter requested that CMS extend the new technology add-on payment for the Zilver® PTX® for FY 2016.

Response: As stated previously, the new technology add-on payment regulations provide that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (§ 412.87(b)(2)). 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 add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362). Consistent with this practice, because the 3-year anniversary date of the product's entry onto the U.S. market will occur during the first half of FY 2016, we are not extending new technology add-on payments for FY 2016.

After consideration of the public comment we received, we are finalizing our proposal to discontinue new technology add-on payments for the Zilver® PTX® for FY 2016 because the technology will no longer be considered new.

f. CardioMEMS™ HF (Heart Failure) Monitoring System

CardioMEMS, Inc. submitted an application for new technology add-on payment for FY 2015 for the CardioMEMS™ HF (Heart Failure) Monitoring System, which is an implantable hemodynamic monitoring system comprised of an implantable sensor/monitor placed in the distal pulmonary artery. Pulmonary artery hemodynamic monitoring is used in the management of heart failure. The CardioMEMS™ HF Monitoring System measures multiple pulmonary artery pressure parameters for an ambulatory patient to measure and transmit data via a wireless sensor to a secure Web site.

The CardioMEMS™ HF Monitoring System utilizes radiofrequency (RF) energy to power the sensor and to measure pulmonary artery (PA) pressure and consists of three components: An Implantable Sensor with Delivery Catheter, an External Electronics Unit, and a Pulmonary Artery Pressure Database. The system provides the physician with the patient's PA pressure waveform (including systolic, diastolic, and mean pressures) as well as heart rate. The sensor is permanently implanted in the distal pulmonary artery using transcatheter techniques in the catheterization laboratory where it is calibrated using a Swan-Ganz catheter. PA pressures are transmitted by the patient at home in a supine position on a padded antenna, pushing one button which records an 18-second continuous waveform. The data also can be recorded from the hospital, physician's office or clinic.

The hemodynamic data, including a detailed waveform, are transmitted to a secure Web site that serves as the Pulmonary Artery Pressure Database, so that information regarding PA pressure is available to the physician or nurse at any time via the Internet. Interpretation of trend data allows the clinician to make adjustments to therapy and can be used along with heart failure signs and symptoms to adjust medications.

The applicant believed that a large majority of patients receiving the sensor would be admitted as an inpatient to a hospital with a diagnosis of acute or chronic heart failure, which is typically described by ICD–9–CM diagnosis code 428.43 (Acute on chronic combined systolic and diastolic heart failure) and the sensor would be implanted during the inpatient stay. The applicant stated that for safety considerations, a small portion of these patients may be discharged and the sensor would be implanted at a future date in the hospital outpatient setting. In addition, there would likely be a group of patients diagnosed with chronic heart failure who are not currently hospitalized, but who have been hospitalized in the past few months for which the treating physician believes that regular pulmonary artery pressure readings are necessary to optimize patient management. Depending on the patient's status, the applicant stated that these patients may have the sensor implanted in the hospital inpatient or outpatient setting.

The applicant received FDA approval on May 28, 2014. The CardioMEMS™ HF Monitoring System is currently described by ICD–9–CM procedure code 38.26 (Insertion of implantable pressure sensor without lead for intracardiac or great vessel hemodynamic monitoring).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the CardioMEMS™ HF Monitoring System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the CardioMEMS™ HF Monitoring System for new technology add-on payments for FY 2015 (79 FR 49940). Cases involving the CardioMEMS™ HF Monitoring System that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 38.26 (Insertion of implantable wireless pressure sensor for intracardiac or great vessel hemodynamic monitoring), which was effective October 1, 2011. With the new technology add-on payment application, the applicant stated that the total operating cost of the CardioMEMS™ HF Monitoring System is $17,750. 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 CardioMEMS™ HF Monitoring System is $8,875.

With regard to the newness criterion for the CardioMEMS™ HF Monitoring System, we considered the beginning of the newness period to commence when the CardioMEMS™ HF Monitoring System was approved by the FDA on May 28, 2014. Because the 3-year anniversary date of the entry of the CardioMEMS™ HF Monitoring System on the U.S. market will occur in FY 2017 (May 28, 2017), we proposed to continue new technology add-on payments for this technology for FY 2016.

Because we are adopting the ICD–10 coding system beginning October 1, 2015, for FY 2016, we proposed to identify and make new technology add-on payments for cases involving the CardioMEMS™ HF Monitoring System using either ICD–10–PCS procedure code 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach) or ICD–10–PCS procedure code 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach). We stated that the maximum payment for a case involving the CardioMEMS™ HF Monitoring System would remain at $8,875 for FY 2016.

We invited public comments on our proposals.

Comment: Commenters supported CMS' proposal to continue new technology add-on payments for the CardioMEMS™ HF Monitoring System for FY 2016. Commenters also supported CMS'proposal to use ICD–10–PCS procedure codes 02HQ30Z and 02HR30Z when making new technology add-on payments for cases involving the CardioMEMS™ HF Monitoring System.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for the

CardioMEMS™ HF Monitoring System for FY 2016. Because we are adopting the ICD–10 coding system beginning October 1, 2015, for FY 2016, we will identify and make new technology add-on payments for cases involving the CardioMEMS™ HF Monitoring System using either ICD–10–PCS procedure code 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach) or ICD–10–PCS procedure code 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach). We note that as discussed in section II.G.3. of the preamble of this final rule, CMS determined that there are additional ICD–10–PCS codes describing the insertion of a pressure sensor monitoring that also are appropriate translations for ICD 9 CM procedure code 38.26. These other ICD–10–PCS codes describe the insertion of a pressure sensor monitoring device utilizing an open approach or a percutaneous endoscopic approach (for the right or left pulmonary artery). However, for purposes of new technology add-on payments for cases involving the CardioMEMS™ HF Monitoring System, as stated above, we will identify cases using either ICD–10–PCS procedure code 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach) or ICD–10–PCS procedure code 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach). The maximum payment for a case involving the CardioMEMS™ HF Monitoring System will remain at $8,875 for FY 2016.

g. MitraClip® System

Abbott Vascular submitted an application for new technology add-on payments for the MitraClip® System for FY 2015. The MitraClip® System is a transcatheter mitral valve repair system that includes a MitraClip® device implant, a Steerable Guide Catheter, and a Clip Delivery System. It is designed to perform reconstruction of the insufficient mitral valve for high-risk patients who are not candidates for conventional open mitral valve repair surgery.

Mitral regurgitation (MR), also referred to as mitral insufficiency or mitral incompetence, occurs when the mitral valve fails to close completely causing the blood to leak or flow backwards (regurgitate) into the left ventricle. If the amount of blood that leaks backwards into the left ventricle is minimal, then intervention is usually not necessary. However, if the amount of blood that is regurgitated becomes significant, this can cause the left ventricle to work harder to meet the body's need for oxygenated blood. Severity levels of MR can range from grade 1+ through grade 4+. If left untreated, severe MR can lead to heart failure and death. The American College of Cardiology (ACC) and the American Heart Association (AHA) issued practice guidelines in 2006 that recommended intervention for moderate/severe or severe MR (grade 3+ to 4+). The applicant stated that the MitraClip® System is ''indicated for percutaneous reduction of significant mitral regurgitation . . . in patients who have been determined to be at prohibitive risk for mitral value surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and in whom existing comorbidities would not preclude the expected benefit from correction of the mitral regurgitation.''

The MitraClip® System mitral valve repair procedure is based on the double-orifice surgical repair technique that has been used as a surgical technique in open chest, arrested-heart surgery for the treatment of MR since the early 1990s. According to the applicant, in utilizing ''the double-orifice technique, a portion of the anterior leaflet is sutured to the corresponding portion of the posterior leaflet using standard techniques and forceps and suture, creating a point of permanent cooptation (''approximation'') of the two leaflets. When the suture is placed in the middle of the valve, the valve will have a functional double orifice during diastole.''

With regard to the newness criterion, the MitraClip® System received a premarket approval from the FDA on October 24, 2013. The MitraClip® System is indicated ''for the percutaneous reduction of significant symptomatic mitral regurgitation (MR >= 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.'' The MitraClip® System became immediately available on the U.S. market following FDA approval. The MitraClip® System is a Class III device, and has an investigational device exemption (IDE) for the EVEREST study (Endovascular Valve Edge-to-Edge Repair Study)—IDE G030061, and for the COAPT study (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Health Failure Patients with Functional Mitral Regurgitation)—IDE G120024. Effective October 1, 2010, ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant) was created to identify and describe the MitraClip® System technology.

On August 7, 2014, CMS issued a National Coverage Decision (NCD) concerning Transcatheter Mitral Valve Repair procedures. We refer readers to the CMS Web site at: *http://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=273* for information related to this NCD.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the MitraClip® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the MitraClip® System for new technology add-on payments for FY 2015 (79 FR 49946). As discussed in the FY 2015 IPPS/LTCH PPS final rule, this approval is on the basis of using the MitraClip® consistent with the NCD. Cases involving the MitraClip® System that are eligible for the new technology add-on payments are currently identified by ICD–9–CM procedure code 35.97. The average cost of the MitraClip® System is reported as $30,000. Under section 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 MitraClip® System is $15,000 for FY 2015.

With regard to the newness criterion for the MitraClip® System, we considered the beginning of the newness period to commence when the MitraClip® System was approved by the FDA on October 24, 2013. Because the 3-year anniversary date of the entry of the MitraClip® System on the U.S. market will occur in FY 2017 (October 24, 2016), we proposed to continue new technology add-on payments for this technology for FY 2016.

Because we are adopting the ICD–10 coding system beginning October 1, 2015, we proposed to identify and make new technology add-on payments for cases involving the MitraClip® System using ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach). We stated that the maximum

payment for a case involving the MitraClip® System would remain at $15,000 for FY 2016.

We invited public comments on our proposals.

Comment: Commenters supported CMS' proposal to continue new technology add-on payments for the MitraClip® System for FY 2016. One commenter, the manufacturer, submitted a revised cost analysis. The commenter noted that the MitraClip® System maps to newly created MS–DRGs 273 and 274 (instead of MS–DRGs 250 and 251), the same MS–DRGs as the WATCHMAN® System (which is discussed in section II.I.5.f. of the preamble of this final rule). The commenter reported that it conducted an analysis using the supplemental thresholds that CMS discussed in the proposed rule for newly created MS–DRGs 273 and 274 and demonstrated that the MitraClip® System meets the cost criterion because the case-weighted average standardized charge per case exceeded the case-weighted threshold. Therefore, the commenter believed that the MitraClip® System continues to meet all three criteria for new technology add-on payments for FY 2016.

Response: We appreciate the commenters' support. In the proposed rule, with regard to the cost criterion for the WATCHMAN® System, we discussed using supplemental thresholds for newly created MS–DRGs 273 and 274 and posted these supplemental thresholds on the CMS Web site. We note that we are maintaining our current policy, which is to use the thresholds issued with each final rule for the upcoming fiscal year (that is, for FY 2017, we will use the thresholds for the updated MS–DRG assignments as reflected in Table 10 issued with this FY 2016 final rule) when making a determination to continue the add-on payment for those new technologies that were approved for the new technology add-on payment from the prior fiscal year.

We did not receive any public comments on the coding and payment of the MitraClip® System for FY 2016.

After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for the MitraClip® System for FY 2016. Because we are adopting the ICD–10 coding system beginning October 1, 2015, we will identify and make new technology add-on payments for cases involving the MitraClip® System using ICD–10–PCS procedure code 02UG3JZ. The maximum payment for a case involving the MitraClip® System will remain at $15,000 for FY 2016.

h. Responsive Neurostimulator (RNS®) System

NeuroPace, Inc. submitted an application for new technology add-on payments for FY 2015 for the use of the RNS® System. (We note that the applicant submitted an application for new technology add-on payments for FY 2014, but failed to receive FDA approval prior to the July 1 deadline.) Seizures occur when brain function is disrupted by abnormal electrical activity. Epilepsy is a brain disorder characterized by recurrent, unprovoked seizures. According to the applicant, the RNS® System is the first implantable medical device (developed by NeuroPace, Inc.) for treating persons diagnosed with epilepsy whose partial onset seizures have not been adequately controlled with antiepileptic medications. The applicant further stated that, the RNS® System is the first closed-loop, responsive system to treat partial onset seizures. Responsive electrical stimulation is delivered directly to the seizure focus in the brain when abnormal brain activity is detected. A cranially implanted programmable neurostimulator senses and records brain activity through one or two electrode-containing leads that are placed at the patient's seizure focus/foci. The neurostimulator detects electrographic patterns previously identified by the physician as abnormal, and then provides brief pulses of electrical stimulation through the leads to interrupt those patterns. Stimulation is delivered only when abnormal electrocorticographic activity is detected. The typical patient is treated with a total of 5 minutes of stimulation a day. The RNS® System incorporates remote monitoring, which allows patients to share information with their physicians remotely.

With respect to the newness criterion, the applicant stated that some patients diagnosed with partial onset seizures that cannot be controlled with antiepileptic medications may be candidates for the vagus nerve stimulator (VNS) or for surgical removal of the seizure focus. According to the applicant, these treatments are not appropriate for, or helpful to, all patients. Therefore, the applicant believed that there is an unmet clinical need for additional therapies for partial onset seizures. The applicant further stated that the RNS® System addresses this unmet clinical need by providing a novel treatment option for treating persons diagnosed with medically intractable partial onset seizures. The applicant received FDA premarket approval on November 14, 2013.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the RNS® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the RNS® System for new technology add-on payments for FY 2015 (79 FR 49950). Cases involving the RNS® System that are eligible for new technology add-on payments are currently identified using the following ICD–9–CM procedure codes: 01.20 (Cranial implantation or replacement of neurostimulator pulse generator) in combination with 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)). According to the applicant, cases using the RNS® System would incur an anticipated cost per case of $36,950. Under § 412.88(a)(2) of the regulations, we limit new technology add-on payments to the lesser of 50 percent of the average costs of the device or 50 percent of the costs in excess of the MS–DRG payment rate for the case. As a result, the maximum new technology add-on payment for cases involving the RNS® System is $18,475.

With regard to the newness criterion for the RNS® System, we considered the beginning of the newness period to commence when the RNS® System was approved by the FDA on November 14, 2013. Because the 3-year anniversary date of the entry of the RNS® System on the U.S. market will occur in FY 2017 (November 14, 2016), we proposed to continue new technology add-on payments for this technology for FY 2016.

Because we are adopting the ICD–10 coding system beginning October 1, 2015, we proposed to identify and make new technology add-on payments for cases involving the RNS® System using the following ICD–10–PCS procedure code combination: 0NH00NZ (Insertion of neurostimulator generator into skull, open approach) in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach). We stated that the maximum payment for a case involving the RNS® System would remain at $18,475 for FY 2016.

We invited public comments on our proposals.

Comment: Commenters supported CMS' proposal to continue new technology add-on payments for the RNS® System for FY 2016. One commenter noted that since FY 2015, additional evidence has been published further demonstrating the safety, effectiveness, and durability of the RNS® System. The commenter cited in

particular a peer-reviewed article that was published in February 2015 in *Neurology,* the journal of the American Academy of Neurology. The commenter stated that this article provides interim results of safety and effectiveness from the 7-year, prospective, long-term, follow-up trial for the RNS System.[8]

In addition, the commenter noted a recently published review and opinion in *Nature Reviews Neurology* entitled ''Epilepsy: Closing the loop for patients with epilepsy'' (by two epilepsy specialists, Kristl Vonck, MD and Paul Boon, MD) that discusses the positive long-term results of responsive neurostimulation and the promise this therapy brings to a complex patient population with limited treatment options.

Response: We appreciate the commenters' support and the citations of the additional supporting information.

We did not receive any public comments on the proposed coding and payment of the RNS® System for FY 2016.

After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for the RNS® System for FY 2016. Because we are adopting the ICD–10 coding system beginning October 1, 2015, we will identify and make new technology add-on payments for cases involving the RNS® System using the following ICD–10–PCS procedure code combination: 0NH00NZ (Insertion of neurostimulator generator into skull, open approach) in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach). The maximum payment for a case involving the RNS® System will remain at $18,475 for FY 2016.

5. FY 2016 Applications for New Technology Add-On Payments

We received nine applications for new technology add-on payments for FY 2016. However, two applications, the Angel Medical Guardian® Ischemia Monitoring Device and Ceftazidime Avibactam (AVYCAZ), were withdrawn from consideration for new technology add-on payments for FY 2016 prior to the publication of this final rule. In addition, in accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval of the technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered. One applicant did not receive FDA approval for its technology, Idarucizumab, by July 1, 2015, and, therefore, is ineligible for consideration for new technology add-on payments for FY 2016. We are not including the descriptions and discussions of these three applications that were included in the FY 2016 proposed rule in this final rule. We note that we did receive public comments on all three of these applications. However, because the applicant either withdrew its application or the technology is ineligible for new technology add-on payments for FY 2016 because the technology did not receive FDA approval by July 1, 2015, we also are not summarizing or responding to these public comments in this final rule. A discussion of the six remaining applications is presented below.

a. Blinatumomab (BLINCYTO™)

Amgen, Inc. submitted an application for new technology add-on payments for Blinatumomab (BLINCYTO™), a bi-specific T-cell engager (BiTE) used for the treatment of Philadelphia chromosome-negative (Ph-) relapsed or refractory (R/R) B-cell precursor acute-lymphoblastic leukemia (ALL), which is a rare aggressive cancer of the blood and bone marrow. Approximately 6,050 individuals are diagnosed with Ph- R/R B-cell precursor ALL in the United States each year, and approximately 2,400 individuals, representing 30 percent of all new cases, are adults. Ph-R/R B-cell precursor ALL occurs when there are malignant transformations of B-cell or T-cell progenitor cells, causing an accumulation of lymphoblasts in the blood, bone marrow, and occasionally throughout the body. As a bi-specific T-cell engager, the BLINCYTO™ technology attaches to a molecule on the surface of the tumorous cell, as well as to a molecule on the surface of normal T-cells, bringing the two into closer proximity and allowing the normal T-cell to destroy the tumorous cell. Specifically, the BLINCYTO™ technology attaches to a cell identified as CD19, which is present on all of the cells of the malignant transformations that cause Ph- R/R B-cell precursor ALL and helps attract the cell into close proximity of the T-cell CD3 with the intent of getting close enough to allow the T-cell to inject toxins that destroy the cancerous cell. According to the applicant, the BLINCYTO™ technology is the first, and the only, bi-specific CD19-directed CD3 T-cell engager single-agent immunotherapy approved by the FDA.

BLINCYTO™ is administered as a continuous IV infusion delivered at a constant flow rate using an infusion pump. A single cycle of treatment consists of 28 days of continuous infusion, and each treatment cycle followed by 2 weeks without treatment prior to administering any further treatments. A course of treatment consists of two phases. Phase 1 consists of initial inductions or treatments intended to achieve remission followed by additional inductions and treatments to maintain consolidation; or treatments given after remission has been achieved to prolong the duration. During phase 1 of a single treatment course, up to two cycles of BLINCYTO® are administered, and up to three additional cycles are administered during consolidation. The recommended dosage of BLINCYTO™ administered during the first cycle of treatment is 9 mcg per day for the first 7 days of treatment. The dosage is then increased to 28 mcg per day for 3 weeks until completion. During phase 2 of the treatment course, all subsequent doses are administered as 28 mcg per day throughout the entire duration of the 28-day treatment period.

With respect to the newness criterion, the BLINCYTO™ technology received FDA approval on December 3, 2014, for the treatment of patients diagnosed with Ph- R/R B-cell precursor ALL, and the product gained entry onto the U.S. market on December 17, 2014. As stated in section II.G.1.a. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule and this final rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. In the proposed rule, we noted that the applicant had applied for a new ICD–10–PCS procedure code at the March 18–19, 2015 ICD–10–CM/PCS Coordination and Maintenance Committee Meeting. In this final rule, we note that the new ICD–10–PCS procedure codes XW03351 (Introduction of Blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1) and XW04351 (Introduction of Blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group1) were established as shown in Table 6B (New Procedure Codes) and will uniquely identify procedures involving the BLINCYTO™ technology. More information on this request and the approval can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html* and the FY 2016 New ICD–10–PCS Codes can be found at the CMS Web site at: *http://www.cms.gov/*

[8] Bergey *et al.,* Long-term treatment with responsive brain stimulation in adults with refractory partial seizures. Neurology. 2015 Feb 24;84(8):810–7.

Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html.

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).

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, we stated in the proposed rule our concern that the mechanism of action of the BLINCYTO™ technology does not appear to differ from those of other bi-specific T-cell engagers, which also attract the cancerous cell within close proximity of a normal T-cell with the intent of allowing the cell to get close enough to inject toxins to destroy the cancerous cell. There are several other BiTEs currently under investigation, including MT110 that are used for the treatment of patients diagnosed with gastrointestinal and lung cancers and are directed towards the EpCAM antigen, as well as MCSP-specific and CD33-specific BiTEs used for treating patients diagnosed with melanoma and acute myeloid leukemia, respectively. We believe that the feature that distinguishes the BLINCYTO™ technology from these other bi-specific T-cell engagers is that it specifically targets the CD19 cell. However, in the proposed rule, we stated that we are concerned that the specificity of the mechanism of action may not be sufficient to distinguish the BLINCYTO™ technology from other bi-specific T-cell engagers and, therefore, the technology bears substantial similarity to these other BiTEs used as current treatment options for Medicare beneficiaries. Further, we stated that determining that the BLINCYTO™ technology meets the newness criterion based on the specificity of the mechanism of action would set a precedent that a drug employing the same mechanism of action could be considered ''new'' based on such specificity when evaluated under the substantial similarity criterion.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant maintained that ICD–9–CM diagnosis codes 204.00 (Acute lymphoid leukemia, without mention of having achieved remission) and 204.02 (Acute lymphoid leukemia in relapse) are used to identify patients who may potentially be eligible for treatment using the BLINCYTO™ technology. Using these diagnosis codes, the applicant researched claims data from the FY 2013 MedPAR file and found cases across a wide spectrum of MS–DRGs, not all of which are related to acute lymphoblastic leukemia. According to the applicant, 42.1 percent of all cases representing patients diagnosed with Ph- R/R B-cell precursor ALL were assigned to 238 MS–DRGs. Therefore, we believe that potential cases involving the BLINCYTO™ technology may be assigned to the same MS–DRG(s) as other cases involving bi-specific T-cell engagers used to treat patients with leukemia.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant maintained in its application that the standard treatment for patients diagnosed with Ph- R/R B-cell precursor ALL currently requires the use of multiple, intensive chemotherapy treatment drugs in combination to induce remission in order to allow the patient the opportunity to proceed to allogenic hematopoietic stem cell transplant (alloHSCT), which is the next stage in the course of treatment and the only known curative option. The applicant asserted that the BLINCYTO™ technology is not substantially similar to other treatment options because it does not involve the treatment of the same, or similar, type of diseases or the same, or similar, patient population. The applicant stated that, although chemotherapy is a successful treatment option to induce remission in patients diagnosed with Ph- R/R B-cell precursor ALL, many of these patients relapse or stop responding to this standard treatment and, therefore, are unable to proceed to alloHSCT, the next stage of treatment. Moreover, chemotherapy toxicities can be cumulative. Therefore, the commenter stated, patients who have received intensive treatments may not be eligible for further intensive chemotherapy treatments and, therefore, are unable to proceed to alloHSCT. The applicant asserted that the BLINCYTO™ technology is an anti-cancer immunotherapy that has shown to be effective in the treatment of a patient population in which chemotherapy has not been successful. Moreover, the applicant asserted that, as an anti-cancer immunotherapy, the BLINCYTO™ technology does not demonstrate the cumulative side-effects typically associated with chemotherapy treatments and, therefore, is a treatment option available to patients who are not eligible for further chemotherapy treatments based on the risks associated with cumulative toxicities. However, in the proposed rule, we stated our concern that this specific patient population is not necessarily distinguishable from the overall patient population of individuals diagnosed with Ph- R/R B-cell precursor ALL, and we are unsure how to identify these patients using administrative claims data.

In summary, we stated in the proposed rule that the BLINCYTO™ technology may be similar to other approved technologies currently available to treat the same patient population and medical disorders and, therefore, may not meet the newness criterion. In addition, we stated that the specific patient population targeted by the applicant may not be sufficiently distinguishable from the overall patient population that may be eligible for treatment using options that are currently available for these types of medical disorders. We invited public comments on if, and how, the BLINCYTO™ technology meets the newness criterion.

Comment: The applicant submitted public comments that responded to CMS' concerns presented in the proposed rule. With regard to CMS' concern that the BLINCYTO™ technology's mechanism of action does not appear to differ from other bi-specific T-cell engagers, the applicant emphasized that there are no other FDA-approved bi-specific T-cell engager constructs currently marketed and readily available to Medicare beneficiaries. Therefore, the applicant stated that there are no previously available technologies to use as comparators for determining whether BLINCYTO™ bears a substantial similarity to other bi-specific T-cell engagers. Furthermore, the applicant believed that the BLINCYTO™ technology's mechanism of action is unique and distinguishable from all other FDA-approved therapies because

it redirects the patient's immune system toward the cancerous cells, which leads to the specifically targeted destruction of these cells. The applicant noted that no other FDA-approved anti-cancer immunotherapy redirects the patient's immune system in such a manner and, therefore, the novelty of the BLINCYTO™ technology's bi-specific T-cell engager mechanism of action extends beyond the target antigen specificity. Therefore, the applicant disagreed with CMS that approving new technology add-on payments for this technology would set a precedent in which a drug employing the same mechanism of action could be considered new based on the specificity of its target antigen.

With regard to CMS' concern that potentially eligible cases involving the BLINCYTO™ technology may be assigned to the same MS–DRG(s) as other cases involving target therapy used to treat patients diagnosed with leukemia, the applicant reiterated that there are currently no other FDA-approved bi-specific T-cell engager constructs available on the U.S. market to treat any patients, including Medicare beneficiaries, who have been diagnosed with Ph- R/R B-cell precursor ALL. As such, the applicant contended that potential cases eligible for the BLINCYTO™ would not be assigned to the same MS–DRG(s) as other cases involving other targeted therapies.

With regard to CMS' concern that the specific population of patients identified by the applicant that may be eligible for treatment using the BLINCYTO™ technology (that is, patients who are ineligible for chemotherapy or for whom chemotherapy has not been successful) is not necessarily distinguishable from the overall patient population of individuals diagnosed with Ph- R/R B-cell precursor ALL, the applicant asserted that the approval of the new unique ICD–10–PCS procedure codes to be used to identify cases involving the BLINCYTO™ technology corroborates the recognizable distinction between the specific patient populations. The applicant believed that, if the BLINCYTO™ technology is approved for new technology add-on payments, CMS would be able to use claims data reporting these new ICD–10–PCS procedure codes to distinguish the population of patients treated with the BLINCYTO™ technology from the broader population of patients diagnosed with Ph- R/R B-cell precursor ALL by using these specific new codes on inpatient hospital claims when the codes become effective October 1, 2015.

Response: We appreciate the details and input provided by the applicant in response to our concerns. We also acknowledge that new ICD–10–PCS procedure codes have been approved to uniquely identify procedures that involve the BLINCYTO™ technology, and that these procedure codes may ultimately be used to distinguish the specific patient population from the overall patient population of individuals diagnosed with Ph- R/R B-cell precursor ALL. After considering the additional information submitted by the applicant in response to our concerns, which supported the technology's uniqueness and documented the lack of an equivalent treatment option for patients diagnosed with Ph- R/R B-cell precursor ALL, who may be ineligible for current treatment options, we agree with the applicant that the BLINCYTO™ technology is not substantially similar to other technologies currently available that also are used in the treatment of patients diagnosed with the same or similar types of conditions. We believe that the BLINCYTO™ technology uses a different mechanism of action than other similar technologies, eligible cases involving treatment using the BLINCYTO™ technology would be grouped to a different MS–DRG than those cases treated with similar technologies, and the BLINCYTO™ technology would be used in the treatment of a different patient population than those currently treated with existing technologies. Therefore, we believe that the BLINCYTO™ technology meets the newness criterion.

Comment: Several commenters, including medical specialty societies, believed that the BLINCYTO™ technology meets the newness criterion. The commenters agreed with the applicant's assertion that there are currently no other bi-specific T-cell engager constructs that are available on the U.S. market, and disagreed with CMS' comparisons between the applicant's technology and products currently approved or under investigation. One commenter stated that it is particularly notable that the BLINCYTO™ technology is the first FDA-approved drug to be used in immunotherapy for the treatment of cancer. The commenter noted that, while other bi-specific T-cell engager constructs are in the development stages, these products have not reached the advanced stages of development, whereas the BLINCYTO™ technology is currently FDA-approved and the subject of phase III clinical trials for the treatment of patients diagnosed with Ph-R/R B-cell precursor ALL. Some commenters believed that the relevant comparison analysis conducted for new technology add-on payment eligibility must be related to treatments that are currently available to Medicare beneficiaries. The commenters stated that it is inappropriate to rely upon comparison analysis that compares a candidate for new technology add-on payments, which requires the technology to have FDA approval as a condition, to technologies or treatments that may potentially become available in the future or that are currently under investigation, and sets an impossible standard to achieve that is also inconsistent with CMS' regulations.

Response: We appreciate the commenters' input. We agree with the commenters that new technology add-on payments are intended to recognize the cost of new items that are not reflected in the Medicare claims data used to set payment rates for MS–DRGs. The costs of treatment options that are currently under development and not available on the U.S. market or to Medicare beneficiaries would not be reflected in the Medicare claims data used to set the payment rates for MS–DRGs. Therefore, these treatment options are not an appropriate comparator for technologies being considered for approval under the new technology add-on payment policy. After considering the additional information submitted by the applicant and the input from other commenters, we have determined that the BLINCYTO™ technology meets the newness criterion.

As we discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24432), with respect to the cost criterion, the applicant researched claims data in the FY 2013 MedPAR file, which contained inpatient hospital discharges from October 1, 2012, to September 30, 2013, and identified cases reporting ICD–9–CM diagnosis codes 204.00 (Acute lymphoid leukemia, without mention of having achieved remission) and 204.02 (Acute lymphoid leukemia in relapse), which represent patients who may potentially be eligible for treatment using the BLINCYTO™ technology. The applicant found 2,649 cases across 246 MS–DRGs, including MS–DRGs 834 through 836 (Acute Leukemia without Major Operating Room Procedure, with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 837 through 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis, with MCC, with CC, and without CC/MCC, respectively), which represent approximately 48.1 percent of all cases with patients diagnosed with Ph- R/R B-

cell precursor ALL. The applicant also found that MS–DRG 809 (Major Hematological and Immunologic Diagnoses Except Sickle Cell Crisis and Coagulations Disorders with CC) and MS–DRG 871 (Septicema or Severe Sepsis without Mechanical Ventilation 96+ Hours with CC) contained cases that further represent 9.8 percent of all cases representing patients diagnosed with Ph- R/R B-cell precursor ALL. The cases assigned to the remaining 238 MS–DRGs represent a combined 42.1 percent of all cases representing patients diagnosed with Ph- R/R B-cell precursor ALL, with no single MS–DRG containing cases representing more than 2.0 percent of all cases representing patients diagnosed with Ph- R/R B-cell precursor ALL. The applicant also noted that when identifying cases that may be eligible for the BLINCYTO™ technology, it excluded any claims for discharges paid by Medicare Advantage plans, as well as any claims submitted by Medicare PPS-exempt cancer hospitals.

Because the applicant was unable to provide a single estimate of the charges that would be avoided by using the BLINCYTO™ technology (that is, additional charges incurred during treatment using other technologies), the applicant conducted its own cost analysis using two scenarios for each group of MS–DRGs. The first scenario assumed that 50 percent of the charges for drugs would be eliminated by using the BLINCYTO™ technology, and the second scenario assumed that 75 percent of the charges for drugs would be eliminated. The applicant further conducted sensitivity analyses for each of the top eight MS–DRGs containing cases eligible for the BLINCYTO™ technology, as well as a sensitivity analysis for all of the other MS–DRGs outside of the top eight to which eligible cases mapped. The applicant then examined the average case-weighted standardized charge per case and the average case-weighted threshold amount for all 2,649 cases identified during FY 2013 across all 246 MS–DRGs, and for 1,533 cases during FY 2013 across the top 8 MS–DRGs to demonstrate that the technology meets the cost criterion.

Under the analysis' first scenario, 50 percent of the charges for drugs incurred by using other technologies were removed in order to exclude the charges associated with the use of these technologies. The applicant determined an average case-weighted threshold amount of $60,278 for the 2,649 Ph- R/R B-cell precursor ALL cases in the 246 MS–DRGs identified using the thresholds in Table 10 in the FY 2015 IPPS/LTCH PPS final rule. The applicant also determined an average case-weighted standardized charge per case of $245,006, or $184,728 above the average case-weighted threshold amount. For the subset of 1,533 cases that mapped to the top 8 MS–DRGs, the applicant determined an average case-weighted threshold amount of $65,478 using the threshold in Table 10 in the FY 2015 IPPS/LTCH PPS final rule. The applicant also determined an average case-weighted standardized charge per case of $249,354, or $183,876 above the average case-weighted threshold amount. Based on the applicant's analyses, we believe that the BLINCYTO™ technology meets the cost criterion under the first scenario.

Under the second scenario, the applicant removed 75 percent of charges for drugs incurred by using other technologies in order to exclude the charges associated with the use of these technologies. The applicant determined an average case-weighted threshold amount of $60,278 for the 246 MS–DRGs identified using the thresholds from Table 10 in the FY 2015 IPPS/LTCH PPS final rule. The applicant determined an average case-weighted standardized charge per case of $239,321, or $179,043 above the average case-weighted threshold amount. For the subset of 1,533 cases that mapped to the top 8 MS–DRGs, the applicant determined an average case-weighted threshold amount of $65,478 using the thresholds from Table 10 in the FY 2015 IPPS/LTCH PPS final rule. The applicant determined an average case-weighted standardized charge per case of $242,423, or $176,945 above the average case-weighted threshold amount. Based on the applicant's analyses, we believe that the BLINCYTO™ meets the cost criterion under the second scenario.

In conducting the above analyses, the applicant summarized the charges from the claims it identified and standardized the charges using an unspecified data source. The applicant then inflated all charges from FY 2013 to FY 2015 using the 10.4427 percent inflation factor used by CMS to update the FY 2015 outlier threshold. In determining the costs for the technology per case, the applicant also assumed that the BLINCYTO™ technology would be administered for 28 days during each inpatient stay. The applicant also assumed a hospital markup of 2.0 percent, and applied this amount to its estimated charges per case.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24432 through 24433), we presented three concerns regarding the applicant's methodology and assumptions used in its cost analyses. We stated that the applicant did not specify whether it used the FY 2015 IPPS final rule impact file or another data source to standardize the charges per case for this technology. We also stated our concern that the applicant did not provide a basis for the hospital markup assumed when conducting its cost analyses. Unless the applicant provided this information, we stated that we are unable to determine whether the cost of the technology per case has been calculated appropriately. Moreover, we stated our concern that including charges representative of a full 28-day treatment cycle is not appropriate for the purpose of calculating the charges associated with the BLINCYTO™ technology in order to determine whether the technology meets the cost criterion. According to the applicant, clinical trial data demonstrate that there are large subsets of patients who require inpatient care for the full 28-day treatment cycle because of the extreme clinical conditions relating to patients diagnosed with Ph- R/R B-cell precursor ALL. However, the applicant also conceded that only 25 percent of patients enrolled in the U.S. clinical trial were hospitalized for the full 28-day treatment cycle, and only 38 percent of these patients were over the age of 65. This caused us concern regarding whether the methodology used by the applicant in its cost analysis is appropriate.

We invited public comments on if, and how, the BLINCYTO™ technology meets the cost criterion, specifically in regard to our concerns related to the applicant's methodology.

Comment: The applicant submitted further information in response to CMS' concerns. The applicant indicated that it used the FY 2015 IPPS final rule impact file and other instructions included in Technical Appendix B of the FY 2016 new technology add-on payment application to standardize the charges per case for potentially eligible cases for the BLINCYTO™ technology representing patients diagnosed with Ph- R/R B-cell precursor ALL under all of the scenarios. The applicant also provided more information regarding the basis of its markup values used when conducting sensitivity analyses to demonstrate that the BLINCYTO™ technology meets the cost criterion. Specifically, the applicant stated that it used a markup of 100 percent, which is a cost-to-charge ratio (CCR) of 0.5, and further noted that the charges for the BLINCYTO™ technology would be included in the pharmacy charge category on an inpatient hospital's claim. The applicant identified the national average cost-to-charge ratio of

0.192 for the pharmacy charge category that was calculated in the FY 2015 IPPS/LTCH PPS final rule. The applicant stated that this CCR indicated that charges in this category were 420 percent higher than the costs. However, the applicant did not believe that a 420-percent markup was appropriate for the purposes of new technology add-on payment MS–DRG case-weighted threshold assessment for the cases eligible for the BLINCYTO™ technology. Therefore, the applicant indicated that it reverted to the use of a more conservative markup of 100 percent in its analyses for eligibility for new technology add-on payments to determine the average case-weighted standardized charges per case. The applicant noted that, if it were to have used the national average markup for the pharmacy charge center of 420 percent, the charges associated with the BLINCYTO™ technology would be significantly higher than that which is indicated in its analyses, further exceeding the MS–DRG case-weighted threshold amount and demonstrating that the BLINCYTO™ technology meets the cost criterion.

Furthermore, the applicant maintained that including charges representative of a full 28-day treatment cycle is appropriate for the purpose of calculating the charges associated with the BLINCYTO™ technology. However, the applicant indicated that it conducted additional sensitivity analyses across both of the original scenarios used in the application in which it assumed no hospital markup on the charges associated with the BLINCYTO™ technology to demonstrate the standardized charges per case under different scenarios for the variable number of inpatient days; a scenario for standardized charges per case using the full 28 inpatient days, standardized charges per case using the mean total inpatient days for cycle 1 (21.2 days), and standardized charges per case using the mean total inpatient days per cycle across all cycles (16.2 days). Based on the results of these sensitivity analyses, the applicant continued to believe that the BLINCYTO™ technology meets the cost criterion, regardless of the number of assumed inpatient days and the associated charge markup. The applicant determined that, prior to the inclusion of any charges associated with the BLINCYTO™ technology, the case-weighted average standardized charge per case under all scenarios exceeds the average case-weighted threshold amounts for the respective MS–DRGs, further demonstrating that the target cases potentially eligible for the BLINCYTO™ technology have significantly higher costs to provide the standard of care.

Response: We appreciate the applicant's submittal of the additional information and input. After reviewing the sensitivity analyses included in the original application and subsequent analyses included in the applicant's public comment, we have determined that the BLINCYTO™ technology meets the cost criterion.

As discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24433 and 24434), with respect to the substantial clinical improvement criterion, the applicant asserted that the BLINCYTO™ technology represents a substantial clinical improvement for the treatment of patients diagnosed with Ph-R/R B-cell precursor ALL because it offers a treatment option for patients who may be unresponsive to currently available options for treatment, decreases the rate of subsequent therapeutic interventions for patients who might not have otherwise achieved remission, and reduces mortality. The applicant provided data analysis results from four sources to demonstrate that the technology represents a substantial clinical improvement. These sources include a historical literature search, a model-based meta-analysis (Study 118427), a historical comparator data (Study 20120310), and a pivotal clinical trial (Study MT 103–211). We summarize the results from each of these sources below.

- The historical literature search revealed that superior regimens among currently used chemotherapeutic options result in a complete remission rate ranging from 18.0 percent to 38.6 percent, a median overall survival rate for patients experiencing early first relapse (<12 months) at 4.7 months, and a median overall survival rate for patients experiencing second or later relapse at 3 months. However, there are several limitations to using recent literature as a historical comparison for studies relating to patients diagnosed with Ph- R/R B-cell precursor ALL, including differences in patient populations or study design characteristics across published studies, which make it difficult to formulate absolute comparisons with regard to data obtained from the BLINCYTO™ pivotal clinical trial. Therefore, the applicant conducted a model-based meta analysis (Studies 118427 and 119384), and a historical comparator study (Study 20120310) to account for these differences.
- In the model-based meta analysis (MBMA), the endpoints of complete remission (CR), duration of complete remission (DCR), and overall survival (OS) rate models were used to predict the efficacy of the BLINCYTO™ technology in cases representing patients diagnosed with Ph- R/R B-cell precursor ALL relative to patients treated using existing therapies. Simulations based on the MBMA for adult patients diagnosed with Ph- R/R B-cell precursor ALL projected a poor outcome with existing salvage therapies, and a significant increase in the proportion of CR, DCR, and OS rates in a population with the same summary prognostic factors as those enrolled in the BLINCYTO™ study MT103–211. For adult patients diagnosed with Ph- R/R B-cell precursor ALL who were treated with existing salvage therapies and having the same summary prognostic factors as those enrolled in the BLINCYTO™ study MT 103–211, the projected proportion of CR was 0.121 (95 percent CI: 0.041 to 0.341), the median DCR rate was 4.9 months (95 percent CI: 2.5 to 9.2 months), and the median OS rate was 3.9 months (95 percent CI: 3.0 to 4.7 months). For adult patients diagnosed with Ph- R/R B-cell precursor ALL having the same summary prognostic factors as those enrolled in the BLINCYTO™ study MT 103–211, treatment using the BLINCYTO™ technology when compared with existing salvage therapies is expected to have an odds ratio for proportion of CR of 3.50 (95 percent CI: 1.63 to 8.40), a hazard ratio for DCR of 0.53 (95 percent CI: 0.30 to 0.89), and a hazard ratio for OS of 0.60 (95 percent CI: 0.47 to 0.76). The applicant maintained that these results suggest that the BLINCYTO™ technology is associated with a reduced mortality rate and improved clinical outcomes when compared to standard chemotherapy treatment options.
- A historical comparator study was also conducted to obtain patient-level data for standard of care treatment options for patients experiencing early first relapse, refractory relapse after HSCT, and second or greater relapse in the same patient population as targeted in the BLINCYTO™ pivotal clinical trial. Study 20120310 was a retrospective pooled analysis of historical data available from 1990 to 2014 on hematological remission and survival rates among patients diagnosed with Ph- R/R B-cell precursor ALL who were treated with standard of care therapies. The primary study endpoint was CR following relapse or salvage treatment; and secondary endpoints included estimates of OS rates, RFS rates, and the proportion of patients

receiving alloHSCT. The weighted median OS rate for 1,112 patients based on available data was 3.3 months (95 percent CI: 2.8 to 3.6 months) and was calculated from the start of the last salvage treatment or the first relapse (if start of the last salvage date was unavailable) until the time of death. The weighted OS rate at 6 and 12 months was 30 percent (95 percent CI: 27 percent to 34 percent) and 15 percent (95 percent CI: 13 percent to 18 percent), respectively. Among the patients who achieved CR based on available data (108 patients), the weighted median RFS rate was 5.0 months (95 percent CI: 1.2 to 6.6 months). Among the 808 patients who received alloHSCT after salvage therapy based on available data, 18 percent (95 percent CI: 15 percent to 21 percent) received alloHSCT following the last line of salvage therapy, and among patients who achieved CR, 7 percent (95 percent CI: 5 percent to 9 percent) received alloHSCT. The applicant maintained that these results highlight the poor health care outcomes for patients treated with standard chemotherapy and that BLINCYTO™ represents a significant improvement.

• BLINCYTO™ study MT 103–211 is a pivotal clinical study providing efficacy data for the BLINCYTO™ technology used for the treatment of adult patients diagnosed with Ph- R/R B-cell precursor ALL. It is a phase 2, single-arm study that included a particularly difficult patient population to treat consisting of patients diagnosed with—Ph- R/R B-cell precursor ALL who experienced either: (1) R/R after remission during 12 months or less of the first salvage treatment; (2) R/R after the first salvage treatment; or (3) R/R within 12 months after receiving alloHSCT. The primary endpoint was the rate of CR plus CRh within the first 2 cycles of treatment using the BLINCYTO™ technology. The key secondary endpoints include best overall response within 2 cycles of treatment using the BLINCYTO™ technology, RFS, time of hematological relapse, OS rates, and the proportion of patients eligible for alloHSCT who underwent the procedure after receiving treatment using the BLINCYTO™ technology. An analysis of data from the pivotal trial showed that 40 percent of patients treated with the BLINCYTO™ technology who achieved CR or CRh were able to proceed to alloHSCT. A secondary analysis from the pivotal study found that in patients who achieved CR or CRh and had a minimal residual disease assessment during the first 2 cycles, the MRD response rate (little or no evidence of disease even at the molecular level) was 82.2 percent. The applicant asserted that this finding is significant because MRD is often a harbinger of relapse and a poor prognostic factor for patients diagnosed with Ph- R/R B-cell precursor ALL.

We stated in the proposed rule our concern that the data provided from the clinical studies are not sufficient to demonstrate that the BLINCYTO™ technology meets the substantial clinical improvement criterion. For example, the BLINCYTO™ study MT 103–211 was not randomized or blinded, and was comprised of a small sample group of 189 patients with a median age of 39 years. We further stated our concern that the sample group studied during the clinical trial is not appropriate to determine if the technology represents a substantial clinical improvement in treatment options available for the Medicare patient population. Moreover, we stated our concern that meaningful conclusions cannot be drawn from the results of this study because of the lack of a control group.

With regard to the applicant's assertion that the BLINCYTO™ technology offers a treatment option for patients who may be unresponsive to currently available treatment modalities, the applicant specifically focused on how the BLINCYTO™ technology represents a treatment option for a patient population in which chemotherapy has proven to be unsuccessful, or for whom intensive chemotherapy treatment is not possible because of the risks associated with exposure to cumulative toxicities. The applicant believed that the MBMA, the historical comparator study, and the BLINCYTO™ study MT 103–211, which is a pivotal clinical trial sufficiently isolate this patient population in order to measure specific health care outcomes. We agreed with this assertion. However, we stated our concerns with the isolated patient population are that it is comprised of and represents a small sample group of patients whose age demographic is much younger than the age demographic of eligible Medicare beneficiaries.

The applicant also asserted that the BLINCYTO™ technology decreases the rate of subsequent therapeutic interventions for patients who might not have otherwise achieved remission. In other words, because treatment with the BLINCYTO™ technology appears to increase the possibility of some patients achieving remission, the applicant maintained that these patients would receive fewer therapeutic interventions and become eligible to receive alloHSCT. We stated that we believe that it is difficult to determine what services and therapeutic interventions these patients would have required if they had not achieved remission, and we are not convinced that treatment using the BLINCYTO™ technology leads to a decrease in additional therapeutic interventions. In the proposed rule, we also noted that patients who successfully achieve remission proceed to alloHSCT and, therefore, receive a different set of subsequent therapeutic interventions.

With regard to the applicant's assertion that the BLINCYTO™ technology reduces mortality rates, we noted that the applicant did not directly capture mortality rates as an endpoint in the BLINCYTO™ pivotal study (MT 103–211), although mortality was analyzed during the other three studies that support the new technology add-on payment application. We noted that the data and the MBMA's results included with the technology's application used an OS odds ratio as a measure of mortality, and were developed from 18 studies published between January 1995 and December 2012. We stated our concern that relying on the results of data using a measure of mortality that is contingent upon studies completed in the 1990s presents a limitation in regard to the methodology used in the applicant's analysis. Advances in overall oncology care over the past 2 decades may invalidate the patient population represented in these studies as a comparison group. Therefore, we stated that we find it difficult to attribute the reduced mortality rate and improved clinical outcomes revealed by these studies to the efficacy of the BLINCYTO™ technology.

We invited public comments on if, and how, the BLINCYTO™ technology meets the substantial clinical improvement criterion, specifically in regard to our specified concerns.

Comment: The applicant submitted public comment in response to CMS' concerns presented in the proposed rule which asserted that the sample size and lack of a control arm in the BLINCYTO™ study MT 103–211is due to the rarity and fatality of Ph- R/R B-cell precursor ALL, which made it difficult to find patients to participate in the trials. Nevertheless, the applicant stated that the BLINCYTO™ study MT 103–211 is the largest Ph- R/R B-cell precursor ALL clinical trial reported to date, and was conducted within the limits of its capabilities because larger studies can only be conducted by national or international cooperative study groups. The applicant also

maintained that the sample size is representative of the Medicare patient population who have been diagnosed with Ph- R/R B-cell precursor ALL in relapse in spite of the median age of 39 years, and patients who were Medicare beneficiaries due to disability. Moreover, the applicant noted that MedPAR data demonstrate that 60 percent of the 479 inpatient stays for patients diagnosed with Ph- R/R B-cell precursor ALL in relapse in FY 2014 were Medicare patients under the age of 65. In addition, the applicant pointed out that single-arm trials are common in Phase II testing, especially when there is a low-volume patient population with patients who have very poor prognosis, such as the patient population represented in the BLINCYTO™ study MT 103–211.

According to the applicant, the design of the pooled analysis of historic data provides a viable measure to determine that the BLINCYTO™ technology represents a substantial clinical improvement as compared to characteristically matched patients in a control arm that were treated with other currently available options that may not be appropriate or for which a patient's status prohibits eligibility. The applicant also conducted propensity score analyses to further investigate and support historical data that was used as a comparator and found that the majority of patients in Study 20120310 were diagnosed and treated in the year 2000 or later. Moreover, the applicant believed that the results of the majority of propensity score analyses demonstrated an improvement in overall survival (OS) compared to standard of care chemotherapy. Further, the applicant defended the weighted value of outcome of OS rates in the BLINCYTO™ study MT103–211 as a commonly used endpoint in oncology trials, and a more clinically meaningful endpoint than mortality rates given the rapidly progressive and fatal nature of Ph- R/R B-cell precursor ALL diagnoses. The applicant asserted that CMS should not use, as a metric to determine if the BLINCYTO™ represents a significant clinical improvement, that additional therapeutic interventions associated with alloHSCT are available, given that alloHSCT is the only way to provide patients with a potential cure for diagnoses of Ph- R/R B-cell precursor ALL.

Response: We appreciate the applicant's submittal of the additional information and the explanation of the study design and endpoints in light of the small and rare population of patients diagnosed with Ph- R/R B-cell precursor ALL. We agree with the applicant that, in view of the MedPAR data and the difficulty in finding enough patients to include in a trial and a comparator arm, the sample group studied during the BLINCYTO™ MT 103–211 pivotal clinical trial sufficiently isolates the patient population that the BLINCYTO™ technology is intended to treat. We also agree with the applicant that, given the challenges of conducting a trial with a control arm and the use of historical comparator data, the BLINCYTO™ study MT 103–211 is a reasonable study to show substantial clinical improvement at this junction. However, if approved for new technology add-on payments, we would continue to monitor ongoing Phase III studies to determine if the substantial clinical improvement demonstrated in the BLINCYTO™ study MT 103–211 continues to exist.

Comment: Several commenters believed that the BLINCYTO™ technology demonstrates significant clinical improvement over existing therapies, and stated that patients who have not responded positively to other treatments have been able to benefit from treatment using the BLINCYTO™ technology and its use creates a bridge to alloHSCT, possibly recognized as a transplant procedure that proves to be a potentially curative treatment. While corroborating the applicant's statements regarding the design of the BLINCYTO™ MT103–211 pivotal trial, one commenter pointed out that a response rate of 43 percent complete remission or complete remission with partial hematologic recovery (CR/CRh) as achieved in the BLINCYTO™ study MT103–211 is impressive using a population of patients diagnosed with relapsed Ph- R/R B-cell precursor ALL. Other commenters acknowledged that, while the BLINCYTO™ has its own set of unique toxicities, such as cytokine release syndrome and neurotoxicity, these conditions are severe in only a small minority of patients. Another commenter stated that its experience with most patients has proven that the use of the BLINCYTO™ technology is well tolerated, and its effects positively contrast to the severe side effects associated with multi-agent chemotherapy salvage regiments that these patients would otherwise experience if access to treatment with the BLINCYTO™ technology were not available. The commenter further noted that, if patients treated using the BLINCYTO™ technology respond positively and it is well-tolerated, the patient has the option of becoming a candidate for alloHSCT. As a result, the commenter pointed out that positive response to treatment using the BLINCYTO™ lessens the need for patient's excessive exposure to toxic multi-agent chemotherapy, which has a lower response rate and the potential to cause complications that can become a preventative for these patients from proceeding to alloHSCT.

Response: We appreciate the applicant's additional information and the commenters' input. As noted by one commenter, we recognize that a 43 percent complete or partial remission rate is impressive using a small sample size of a population of patients diagnosed with Ph- R/R B-cell precursor ALL. We also acknowledge that the treatment of patients using currently available combination chemotherapy, or the standard treatment for this disease, has an equivalent or lower rate of complete or partial remission, as well as excessively exposes patients to toxicities that may often be severe. Therefore, we believe that the BLINCYTO™ technology offers a treatment option for Medicare beneficiaries that represents a substantial clinical improvement over existing treatment options for patients who are unresponsive to currently available treatment options and allows many patients the opportunity to access alternative less invasive options, and also provides a bridge to alloHSCT, the only potentially curative option for patients who have been diagnosed with Ph- R/R B-cell precursor ALL. We agree with the commenters that the BLINCYTO™ technology represents a substantial clinical improvement over existing technologies in a patient population diagnosed with Ph- R/R B-cell precursor ALL, or whose only other treatment option for bridging to alloHSCT has potentially worse outcomes and excessive exposure to toxicities.

After consideration of the public comments we received, we have determined that the BLINCYTO™ technology meets all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for the BLINCYTO™ technology for FY 2016. Cases involving the BLINCYTO™ technology that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW03351 or XW04351.

Comment: Although the applicant considered the cost and expected use based on a variable number of days for treatment in its costs analyses, the applicant recommended that CMS consider and use the cost of the full 28-day inpatient treatment cycle as the

expected length of treatment when determining the maximum new technology add-on payment for cases involving the BLINCYTO™ rather than the average cost of lesser number of days used as other variables. The applicant noted that a single treatment cycle using the BLINCYTO™ consists of 28 days of continuous infusion, and each cycle of treatment is separated by a 2-week treatment-free interval. The applicant recommended that the initial dose of BLINCYTO™ in the first cycle consist of 9 mcg/day for week 1 (first 7 days) of treatment and the dose is increased to 28 mcg/day starting at week 2 through week 4 of the first cycle. The applicant further stated that all subsequent cycles are recommended to be dosed at 28 mcg/day throughout the entire 28-day treatment period. As further explained by the applicant, for each cycle of therapy, a patient will receive one vial (35 mcg) of BLINCYTO™ per day over the entire 28-day treatment period.

According to the applicant, if the maximum new technology add-on payment for cases involving the BLINCYTO™ is capped at a level less than 50 percent of the estimated costs of the full 28-day inpatient treatment cycle, the actual add-on payment would be well below the cost of care for some patients. The applicant believed that if CMS set the maximum add-on payment amount based on the full 28-day treatment cycle, it would avoid the risk of underpaying or overpaying for cases involving the BLINCYTO™ or cases not performed in the inpatient setting and paid for under the IPPS that have fewer inpatient days. The applicant explained that during the treatment cycle using the BLINCYTO™, infusion bags are changed every 24 to 48 hours and hospitals would only be charged for the number of bags of BLINCYTO™ that are used during the inpatient stay under the IPPS and when the product is provided while the patient is admitted. Therefore, for those patients who have an inpatient length of stay that is shorter than the 28-day treatment cycle, the applicant stated that the add-on payment would be based only on the costs associated with the number of days that the patient received treatment using the BLINCYTO™ technology in the inpatient setting. The applicant stated that CMS would not be paying the maximum add-on payment amount in those cases and pointed out that CMS would only pay the maximum add-on payment amount for cases that require the patient to remain in the inpatient setting in order to receive treatment using the BLINCYTO™ technology for the entire 28-day treatment cycle.

The applicant stated that it recognized that CMS may be concerned that it may not be able to differentiate which charges on claims should trigger eligibility for the new technology add-on payment. In addition, the applicant referenced section 1886(d)(5)(K)(ii)(III) of the Act, which refers to an additional payment in an amount that adequately reflects the estimated average cost of such service or technology, and CMS's policy of limiting payment to 50 percent of the cost of the technology, as codified under § 412.88(a)(2)(i) of our regulations. However, the applicant believed that limiting new technology add-on payments for cases involving the BLINCYTO™ technology if the maximum payment amount is based on an expected average number of days of care may inappropriately limit the total payment for the case, which the applicant asserted is inconsistent with the statute. The applicant further stated that if the new technology maximum add-on payment is capped at a level less than 50 percent of the estimated costs of case based on the full 28-day cycle, it may negatively impact access to care for those patients who require a longer inpatient admission. The applicant explained that, in the case of the BLINCYTO™ technology, the cost of the technology is likely to be a significant driver in the overall cost of the admission and it is less likely that other charges unrelated to the use of the BLINCYTO™ technology would be the primary driver for an increased new technology add-on payment amount. The applicant indicated that using a methodology that relies on the average cost of a case that is based on a number of treatment days that is less than the 28-day treatment cycle to establish the maximum add-on payment amount would disadvantage any hospital that treats Medicare beneficiaries who remain admitted to the hospital for longer than the mean total inpatient days per cycle observed in clinical trials. Therefore, the applicant encouraged CMS to set the maximum new technology add-on payment amount based on the full 28-day course of therapy.

Response: We disagree with the applicant that it would be most appropriate to determine the maximum new technology add-on payment amount for a case based on the recommended estimated 28-day treatment cycle. As the applicant acknowledged, in cases where there are different dosages administered on different days and different device sizes being used, it would be difficult for us to differentiate which charges on claims would trigger the case's eligibility for the new technology add-on payment. It is historical practice for CMS to make the new technology add-on payment based on the average cost of the technology and not the maximum. For example, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53358), we approved new technology add-on payments for DIFICID™ based on the average dosage of 6.2 days rather than the maximum 10 day dosage. In addition, as discussed below, based on the clinical trial data, the weighted average of cycle 1 and 2 treatment length is 17 days, as none of the five cycles typically reach 28 days. Just as some cases' length of stay will be above the weighted mean and a hospital's costs may exceed the payment for these cases, other cases' length of stay may be below the weighted mean and hospitals costs would be lower than what the hospital is paid. Therefore, because we are not able to differentiate which charges on claims would trigger the case's eligibility for the new technology add-on payment if we based the maximum new technology add-on payment amount for a case on a 28-day treatment cycle, we believe that it is appropriate to use the average cost and the weighted mean of the first two cycles to establish the maximum new technology add-on payment for the BLINCYTO™ technology. However, the applicant is welcome to submit additional data for FY 2017 that demonstrates changes to the weighted mean of the first two cycles.

In order to establish the maximum new technology add-on payment amount for a case involving the BLINCYTO™ technology for FY 2016, we used the weighted average of the cycle 1 and cycle 2 observed treatment length. Specifically, in the Phase II trial, the most recent data available, 92 patients received cycle 1 for an average length of 21.2 days, and 52 patients received cycle 2 for an average length of 10.2 days. The weighted average of cycle 1 and 2 treatment length is 17 days. We note that a small number of patients also received 3 to 5 treatment cycles. However, based on the data provided, these cases do not appear to be typical at this point and we excluded them from this calculation. We note that, if we include all treatment cycles in this calculation, the weighted average number of days of treatment is much lower, 10 days. Using the clinical data provided by the applicant, we believe that setting the maximum new technology add-on payment amount for a case involving the BLINCYTO™

technology for FY 2016 based on a 17-day length of treatment cycle is representative of historical and current practice. For FY 2107, if new data on length of treatment are available, we would consider any such data in evaluating the maximum new technology add-on payment amount.

In the application, the applicant estimated that the average Medicare beneficiary would require a dosage of 9mcg/day for the first 7 days under the first treatment cycle, followed by a dosage of 28mcg/day for the duration of the treatment cycle, as well as all days included in subsequent cycles. All vials contain 35mcg at a cost of $3,178.57 per vial. The applicant noted that all vials are single-use. Therefore, we have determined that cases involving the use of the BLINCYTO™ technology would incur an average cost per case of $54,035.69 (1 vial/day × 17 days × $3,178.57/vial). Under 42 CFR 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 the BLINCYTO™ is $27,017.85 for FY 2016.

b. DIAMONDBACK 360 Coronary Orbital Atherectomy System

Cardiovascular Systems, Inc. submitted an application for new technology add-on payments for the DIAMONDBACK 360® Coronary Orbital Atherectomy System (OAS) (DIAMONDBACK® Coronary OAS) for FY 2016. The DIAMONDBACK® Coronary OAS is a percutaneous orbital atherectomy system used to facilitate stent delivery in patients who have been diagnosed with coronary artery disease and severely calcified coronary artery lesions. The system uses an electrically driven, diamond-coated crown to reduce calcified lesions in coronary blood vessels. The components of the DIAMONDBACK® Coronary OAS are: (1) The DIAMONBACK 360® Coronary Orbital Atherectomy Device (OAD); (2) the VIPERWIRE Advance Coronary Guide Wire; (3) the VIPERSLIDE Lubricant; and (4) the Orbital Atherectomy System Pump. The DIAMONBACK 360® OAD is designed to track exclusively over the VIPERWIRE, which, in turn, uses the VIPERSLIDE Lubricant to reduce the friction between the drive shaft of the DIAMONBACK 360® OAD and the VIPERWIRE. The Orbital Atherectomy System Pump provides the saline pumping mechanism and power to the DIAMONBACK 360® OAD. All DIAMONDBACK® Coronary OAS devices are single use and provide sterile application, except for the pump.

With respect to the newness criterion, the DIAMONDBACK® Coronary OAS received FDA pre-market approval as a Class III device on October 21, 2013. As stated in section II.G.1.a. of the preamble of the proposed rule and this final rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. In the proposed rule, we indicated that the applicant had applied for a new ICD–10–PCS procedure code for consideration at the March 18–19, 2015 ICD–10–CM/PCS Coordination and Maintenance Committee Meeting. In this final rule, we note that the following new ICD–10–PCS procedure codes have been established to uniquely identify the procedures involving the DIAMONDBACK® Coronary OAS, effective October 1, 2015: X2C1361 (Extirpation of matter from coronary artery, one site using orbital atherectomy technology, percutaneous approach, new technology group 1); X2C1361 (Extirpation of matter from coronary artery, two sites using orbital atherectomy technology, percutaneous approach, new technology group 1); X2C2361 (Extirpation of matter from coronary artery, three sites using orbital atherectomy technology, percutaneous approach, new technology group 1); and X2C3361 (Extirpation of matter from coronary artery, four or more sites using orbital atherectomy technology, percutaneous approach, new technology group 1). More information on this request and our approval can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html* and the FY 2016 New ICD–10–PCS codes can be found at the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html.*

According to the applicant, the DIAMONDBACK® Coronary OAS is the only atherectomy device that uses centrifugal force and orbital motion and, therefore, is not represented by the rotational, directional, or laser atherectomy device categories (as exemplified by Boston Scientific's Rotablator system, the SilverHawk/Covidient devices, and the Spectranetics ELCA Coronary Laser, respectively). In addition, the applicant asserted that the DIAMONDBACK® Coronary OAS is the first and only device approved for use in the United States as a treatment for patients who have been diagnosed with severely calcified coronary artery lesions to facilitate stent delivery and optimal deployment. Therefore, the applicant believed that the DIAMONDBACK® Coronary OAS meets the newness criterion.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24439), we presented our concern that, in addition to patients who have been diagnosed with severely calcified coronary artery lesions, the applicant also indicated that the DIAMONDBACK® Coronary OAS may be used in the treatment of patients who *do not* have severely calcified coronary artery lesions (for example, patients for whom the degree of calcification may not be severe) and that this technology may be substantially similar to the rotational, directional, and laser atherectomy devices that are already on the U.S. market for the treatment of such patients. 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.

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 maintained that the technology uses a differential sanding mechanism of action to remove plaque while potentially minimizing damage to the medial layer of the vessel. According to the applicant, this mechanism of action is the only one among atherectomy devices to use centrifugal force and orbital motion and, therefore, is not represented by the rotational, directional, or laser atherectomy device categories. We stated in the proposed rule that the applicant did not include with its application data to show the effectiveness of the orbital mechanism of the DIAMONDBACK® Coronary OAS compared to the effectiveness of the rotational, directional, and laser mechanisms of similar devices used in treating patients with calcified coronary artery lesions. Therefore, we stated that we could not determine if the device's mechanism of action is unique among atherectomy devices as the applicant claimed.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant determined that coronary atherectomy cases for which the DIAMONDBACK® Coronary OAS technology would be appropriate are assigned to MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents); MS–DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC); MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents); MS–DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC); MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC), and MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC). In the proposed rule, we stated our concern that potential cases involving the DIAMONDBACK® Coronary OAS would be assigned to the same MS–DRGs as other cases that use atherectomy devices currently available on the U.S. market.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant maintained in its application that the DIAMONDBACK® Coronary OAS is the first and only device approved for use in the United States as a treatment for severely calcified coronary lesions. According to the applicant, advances in current stent technology have allowed most patients with coronary lesions to be treated effectively with relatively favorable long-term outcomes. However, there remain subsets of the patient population that are still challenging to treat, including patients with severe coronary calcification. According to the applicant, the DIAMONDBACK® Coronary OAS is the only atherectomy device currently available to treat this patient population because it is the first and only device approved for use in the United States for severely calcified coronary lesions. However, in the proposed rule, we stated our concern that other devices currently available on the U.S. market may not necessarily be contraindicated for use in treating patients with severe coronary calcification. Specifically, we were not sure if patients with less than severe coronary calcification could be appropriately treated using the DIAMONDBACK® Coronary OAS or other atherectomy devices currently available on the U.S. market in order to determine if the DIAMONDBACK® Coronary OAS treats a different patient population as the applicant claimed.

We invited public comments on if, and how, the DIAMONDBACK® Coronary OAS meets the newness criterion.

Comment: In a public comment, the applicant asserted that the DIAMONDBACK® Coronary OAS is not substantially similar to the rotational, laser, or other atherectomy devices currently on the U.S. market. Further, with respect to our concern about the device's mechanism of action, the applicant stated that the lack of data comparing the performance of the DIAMONDBACK® Coronary OAS to other atherectomy devices is primarily a result of the FDA's decision to not allow a controlled trial to be conducted that compared the efficacy and effects of FDA-approved technologies or devices and the efficacy and effects of another treatment that is not FDA-approved. Therefore, the applicant stated, a controlled trial was not conducted because currently there are no other technologies specifically approved for the treatment of severely calcified coronary lesions in the United States.

The applicant also believed the CMS has set a precedent, in the past, by approving devices for new technology add-on payments that treated conditions that were assigned to the same MS–DRGs as other devices, which were reported using the same ICD–9–CM procedure codes. The applicant noted as an example the recent approval of the Zilver® PTX Drug-Eluting Peripheral Stent, a drug-eluting stent used for the treatment of patients diagnosed with superficial femoral arteries, procedures that are assigned to MS–DRGs 252, 253, and 254, all of which contain other drug-eluting stents (78 FR 50583). As a result, the applicant believed that CMS' concern and position in regard to contraindication would have precluded the Zilver® PTX technology from being approved for new technology add-on payments because there were other stents available on the U.S. market that also were not contraindicated to treat patients diagnosed with superficial femoral arteries, as well as other devices approved and available to treat patients diagnosed with superficial femoral arteries. The applicant noted that the current application for new technology add-on payments is for use of the DIAMONDBACK® Coronary OAS in the treatment of patients diagnosed with severely calcified lesions, which the applicant believed would be appropriately identified using the new ICD–10 codes it requested. Therefore, the applicant believed that isolating this patient population by using the ICD–10 codes to identify procedures involving the DIAMONDBACK® Coronary OAS also may prevent diffusion of the use of the device into inappropriate patient populations.

Response: We appreciate the applicant's additional input. However, we remain concerned that the DIAMONDBACK® Coronary OAS is substantially similar to other atherectomy devices that are currently available on the U.S. market. Specifically, we are concerned that the orbital mechanism of action performs the same basic motion and has the same function as the current standard of care, rotational atherectomy devices. Although the applicant stated that FDA did not grant approval to conduct a trial comparing approved versus non-approved technologies, we note that the FDA does not prohibit manufacturers from performing other trials outside of the trials included under its approval process. Moreover, we are concerned that the patient population of cases that may be eligible for treatment using the DIAMONDBACK® Coronary OAS also currently has access to other atherectomy devices and similar technologies that are also used in the treatment of similar conditions. We acknowledge that the Zilver® PTX technology was approved for new technology add-on payments and that procedures involving this technology are assigned to MS–DRGs that contain other procedures involving stents. Also, we acknowledge that the Zilver® PTX was approved for new technology add-on payments when it had been assigned to the same MS–DRGs as other stents, and that the Zilver® PTX potentially could have been used to treat a similar or same patient population as other technologies used in procedures involving stents. However, the Zilver® PTX was also the first drug-eluting stent technology at the time we approved the application for new technology add-on payments and, therefore, its new mechanism of action set the basis and precedent for new technology add-on payment approval of similar technologies. Absent this, we would have had the same concerns about contraindication for the Zilver® PTX technology as we currently have for the DIAMONDBACK® Coronary OAS. After consideration of the public comments we received, we remain concerned if the DIAMONDBACK® Coronary OAS meets the newness criteria.

With respect to the cost criterion, the applicant determined that cases representing patients who have been treated with transluminal coronary

atherectomy for which the DIAMONDBACK® Coronary OAS technology is appropriate map to MS–DRGs 246 through 251 as noted earlier in this section. The applicant searched the claims data in the FY 2013 MedPAR file for cases assigned to these six MS–DRGs (which contained claims for inpatient hospital discharges from October 1, 2012 to September 30, 2013) and identified 5,443 claims for cases reporting ICD–9–CM procedure code 17.55. The applicant indicated that it further examined the claims data for the cases that also reported ICD–9–CM diagnosis code 414.4, and identified 250 claims for cases with a diagnosis of calcified coronary lesion. The applicant stated that it applied the standard trims used by CMS when selecting cases for IPPS rate calibration. Therefore, it included cases from IPPS hospitals, including hospitals located in Maryland, and excluded cases paid by Medicare Advantage plans, statistical outlier cases, and cases from hospitals that did not submit charges in a sufficiently broad range of revenue centers.

The applicant reported that it conducted 16 sensitivity analyses based on four areas of uncertainty: whether to include all coronary atherectomy cases in the analysis or only those cases that reported calcified coronary artery lesions; whether to consider a lower value or higher value as the acquisition cost of a typical atherectomy catheter; whether to use the full cost of the DIAMONDBACK® Coronary OAS catheter and materials or only the cost of the catheter alone; and whether to include or exclude a factor to inflate costs to FY 2015 costs. Based on the result of the sensitivity analyses with all 16 combinations of the values that the applicant performed, the applicant reported that it determined that the average case-weighted standardized charge per case for the DIAMONDBACK® Coronary OAS would exceed the average case-weighted threshold amounts for MS–DRGs 246 through 251 in Table 10 of the FY 2015 IPPS/LTCH PPS final rule. According to the applicant, the average case-weighted standardized charge per case using the DIAMONDBACK® Coronary OAS device exceeds the average case-weighted threshold amounts for MS–DRGs 246 through 251 in Table 10 by approximately $6,000 to $15,000, depending on the results determined by using the combination of values of the four areas of uncertainty. As described below, the applicant believed that using the scenario that produced the lowest difference between the average case-weighted standardized charge per case determined by the applicant's analyses and the average case-weighted threshold amounts for MS–DRGs 246 through 251 from Table 10 in the FY 2015 IPPS/LTCH PPS final rule still exceeded the Table 10 threshold amounts by $5,803.

Using the scenario that produced the lowest difference between the average case-weighted standardized charge per case determined by the applicant and the average case-weighted threshold amount in the FY 2015 IPPS/LTCH PPS final rule Table 10, the applicant included all cases reporting coronary atherectomy (specifically, the 5,443 cases reported with ICD–9–CM procedure code 17.55) in this analysis. The applicant removed the costs of the other specific technologies used during these procedures; that is, the applicant removed the higher of the two standard catheter costs, and added the full cost of the DIAMONDBACK® Coronary OAS catheter alone. To estimate the cost for the new technology, the applicant divided the projected cost per patient by the national average CCR for supplies (0.292) included in the FY 2015 IPPS/LTCH PPS final rule. This resulted in an average case-weighted average standardized charge per case of $86,080. The applicant stated that it did not apply an inflation factor to convert the FY 2013 costs to FY 2015 costs for this analysis. However, in other analyses, the applicant used the 2-year inflation factor of 10.44 percent taken from the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379), which was the final inflation factor used in the CMS outlier threshold calculation for the applicable fiscal year. The applicant then determined that its average case-weighted standardized charge per case exceeded the average case-weighted threshold amounts for MS–DRGs 246 through 251 in Table 10 of the FY 2015 IPPS/LTCH PPS final rule by $5,803. The applicant maintained that all of the results of the analyses using this methodology that were included in its application likewise exceeded the Table 10 threshold amounts for these MS–DRGs and, therefore, demonstrated that the DIAMONDBACK® Coronary OAS meets the cost criterion.

Using the scenario that produced the lowest difference between its average case-weighted standardized charge per case and the average case-weighted threshold amounts for MS–DRGs 246 through 251 from the FY 2015 Table 10 for the analysis of the subgroup of cases representing patients who have severely calcified coronary artery lesions, the applicant reported that it included all of the cases that report coronary atherectomy that also reported diagnosis of calcified coronary lesions (250 cases reporting ICD–9–CM procedure code 414.4). As in the previous scenario, the applicant removed costs of the other specific technologies used during these other procedures; that is, the applicant removed the higher of the two standard catheter costs, and added the full cost of the DIAMONDBACK® Coronary OAS catheter alone. To estimate the costs for the new technology, the applicant divided the projected cost per patient by the national average CCR for supplies (0.292) in the FY 2015 IPPS/LTCH PPS final rule. This resulted in an average case-weighted standardized charge per case of $86,779. The applicant did not apply an inflation factor to convert the FY 2013 costs to FY 2015 costs for this analysis. The applicant then determined that the average case-weighted standardized charge per case exceeded the FY 2015 Table 10 threshold amount of $80,807 by $5,972. The applicant maintained that all of the results of the analyses using this methodology that were included in its application likewise exceeded the Table 10 threshold amounts for these MS–DRGs and, therefore, demonstrated that the DIAMONDBACK® Coronary OAS meets the cost criterion.

In the proposed rule, we questioned some of the assumptions underlying the four areas of uncertainty that were the basis for the applicant's sensitivity analyses. We stated that we would like to know the basis of the higher value that the applicant considered to be a possible acquisition cost of a typical atherectomy catheter. We also stated our concern that the applicant did not provide a basis for determining the two values it used to remove the costs associated with the other specific technologies that may have been used during the cases included in the analysis. We invited public comments on if, and how, the DIAMONDBACK® Coronary OAS meets the cost criterion.

Comment: The applicant (the manufacturer) addressed CMS' concerns that were presented in the proposed rule by conducting another cost analysis. The applicant reported that it determined the cost of the existing technology by utilizing data from the Millennium Research Group, which publishes an annual report in the coronary market. The applicant referenced the average sales price in 2015 for rotational atherectomy, which is the standard device currently used in coronary atherectomy procedures. The applicant stated that the additional analysis included the cost for associated supplies and the average sales price of the rotational atherectomy catheter. The applicant maintained that, in both cost

analyses, the DIAMONDBACK® Coronary OAS exceeded the cost threshold and, therefore, meets the cost criterion.

Response: We appreciate the applicant's response and subsequent analyses, which we believe respond to the concerns we raised in the proposed rule.

After consideration of the applicant's response, we have determined that the DIAMONDBACK® Coronary OAS meets the cost criterion.

As discussed in the proposed rule, in regard to substantial clinical improvement, the applicant maintained that the DIAMONDBACK® Coronary OAS offers a treatment option for a patient population that has been diagnosed with severely calcified coronary arteries that are ineligible for currently available treatments and results in improved clinical outcomes for patients who have been diagnosed with complex coronary artery disease related to severely calcified coronary arteries. The applicant also stated that the DIAMONDBACK® Coronary OAS device significantly improves clinical outcomes for this patient population when compared to currently available treatment options, including reduced mortality, a reduced rate of device-related complications, a decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process), a decreased number of future hospitalizations or physician visits, more rapid beneficial resolution of the disease process treatment because of the use of the device, decreased pain, bleeding, or other quantifiable symptoms, and reduced recovery time.

The applicant included data from its ORBIT II study to demonstrate that the technology represents substantial clinical improvement over currently available treatment options, including improvement in mortality rates, major adverse cardiac event (MACE) rates, revascularization rates, and cost savings. According to the applicant, its ORBIT II study was a pivotal clinical study to evaluate the safety and effectiveness of the DIAMONDBACK® Coronary OAS in treating a subset of patients who have severely calcified coronary artery lesions. The applicant explained that the ORBIT II study was a prospective, multicenter, non-blinded clinical trial that enrolled 443 consecutive patients who have been diagnosed with severely calcified coronary lesions at 49 U.S. sites from May 25, 2010 to November 26, 2012, in which the DIAMONDBACK® Coronary OAS was used to prepare patients who had severely calcified coronary lesions for stent placement. According to the applicant, the DIAMONDBACK® Coronary OAS produced clinical outcomes that exceeded its ORBIT II study's two primary safety and efficacy endpoints within a patient population. The primary safety endpoint was 89.6 percent freedom from 30-day MACE, compared with the performance goal of 83 percent. The primary efficacy endpoint (residual stenosis <50 percent post-stent without in-hospital MACE) was 88.9 percent, compared with the performance goal of 82 percent. The applicant stated that, during the trial, stent delivery after use of the DIAMONDBACK® Coronary OAS occurred successfully in 97.7 percent of cases with <50 percent residual stenosis in 98.6 percent of the patients in the study. The applicant further stated that low rates of in-hospital Q-wave MI, cardiac death, and target vessel revascularization also were reported. The applicant believed that the results of its ORBIT II study met both the primary safety and efficacy endpoints by significant margins and not only helped to facilitate stent delivery, but also improved both acute care and 30-day clinical outcomes compared to historical controls.

The applicant also compared the results of its ORBIT II study with historical study data that measured the performance of other coronary atherectomy devices used in the treatment of patients who have moderate to severely calcified coronary lesions. According to the applicant, the death and revascularization rates reported in the ORBIT II study were much lower than those rates reported in the literature for patients who had severely calcified coronary lesions. For example, inpatient cardiac death rates were reported on one reported study in the literature (Mosseri, et al.) as 1.6 percent and in another reported study (Abdel-Wahab, et al.) as 1.7 percent, while another study report (Clavijo, et al.) reported death at 30 days as 2.6 percent and 1.5 percent for RA + DES and DES, respectively.[9] [10] [11] The applicant maintained that, compared to these historical study data, the data results of the ORBIT II study demonstrated much lower cardiac death rates of 0.2 percent in-hospital and 0.2 percent at 30 days. The applicant further reported that the results of its ORBIT II study showed lower mortality rates at 9 months and 1 year (3 percent and 4.4 percent, respectively) compared to previously reported rates (5.0 percent and 5.85 percent at 9 months and 6.3 percent at 1 year). The study report by Mosseri, et al. also reported a 1.6 percent in-hospital target lesion revascularization rate (TLR) in a patient population with more superficial calcification,[12] whereas the study report by Clavijo, et al. reported a 1.3 percent 30-day TLR rate for the RA + DES group.[13] In contrast, the applicant reported that the results of the ORBIT II study showed a lower TLR rate of 0.7 percent (both in-hospital and 30-day), even though more patients who had severely calcified coronary lesions were included in the study, and the patients were older and had more comorbidities. The applicant stated that, at 1-year, the results of the ORBIT II study showed a higher freedom from TVR/TLR rate (94.1 percent) compared to previously reported rates (81.7 percent to 91.3 percent), even though patients who had more severely calcified coronary lesions were included in the ORBIT II study. According to the applicant, the MACE rate of 16.4 percent indicated in the results of the ORBIT II study was lower than the rate of the ROTAXUS (24.4 percent) and ACUITY/HORIZONS (19.9 percent) trials despite the use of a less stringent standard of severe calcification in the latter studies.[14] [15] Further, the

[9] Mosseri M, Satler LF, Pichard AD, Waksman R. Impact of vessel calcification on outcomes after coronary stenting. *Cardiovasc Revascularization Med Mol Interv. 2005;6(4):147–153.*

[10] Abdel-Wahab M, Richardt G, Joachim Buttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: The randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial. *JACC Cardiovasc Interv.* 2013;6(1):10–19.

[11] Clavijo LC, Steinberg DH, Torguson R, et al. Sirolimus-eluting stents and calcified coronary lesions: clinical outcomes of patients treated with and without rotational atherectomy. *Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv.* 2006;68(6):873–878.

[12] Mosseri M, Satler LF, Pichard AD, Waksman R. Impact of vessel calcification on outcomes after coronary stenting. *Cardiovasc Revascularization Med Mol Interv. 2005;6(4):*147–153.

[13] Clavijo LC, Steinberg DH, Torguson R, et al. Sirolimus-eluting stents and calcified coronary lesions: clinical outcomes of patients treated with and without rotational atherectomy. *Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv.* 2006;68(6):873–878.

[14] Genereux P, Madhavan MV, Mintz GS, et al. Ischemic outcomes after coronary intervention of calcified vessels in acute coronary syndromes. Pooled analysis from the HORIZONS–AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) TRIALS. *J Am Coll Cardiol.* 2014;63(18):1845–1854.

[15] Abdel-Wahab M, Richardt G, Joachim Buttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: The randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial. *JACC Cardiovasc Interv.* 2013;6(1):10–19.

applicant reported that patients in the ORBIT II study experienced a lower rate of device-related complications (such as dissection, abrupt closure, and perforation) compared to rates in the historical studies. Overall, the applicant asserted that a comparison of data from the ORBIT II study and the data from historical studies demonstrates that patients in the ORBIT II study had more severe calcium coronary lesions and potentially were more difficult to treat, although they experienced better outcomes.

In the proposed rule, we stated our concern that the ORBIT II study conducted by the applicant lacked a control arm. The applicant asserted in its original application that, although other FDA-approved coronary atherectomy products are available, none of them are indicated for the treatment of patients who have severely calcified coronary arteries and, therefore, could not be used as a control. The applicant believed that it accounted for this study limitation by comparing the results of the ORBIT II study to historical control subjects documented in published reports. However, we stated that we continue to be concerned that meaningful conclusions cannot be drawn from a study that did not include a comparator group. Moreover, we questioned the reliability of comparing data from the ORBIT II study to historical study data because different definitions of severe calcification used in each study can make absolute comparisons difficult and/or invalid.

We invited public comments on if, and how, DIAMONDBACK® Coronary OAS meets the substantial clinical improvement criterion.

Comment: Several commenters believed that the DIAMONDBACK® Coronary OAS meets the substantial clinical improvement criterion and, therefore, recommended that CMS approve the application for new technology add-on payments for FY 2016. In particular, the applicant stated in its public comment that the single-arm ORBIT II trial and historical comparator data are sufficient to demonstrate substantial clinical improvement because the results show that the DIAMONDBACK® Coronary OAS performed better than other atherectomy devices on key safety and efficacy endpoints despite a more rigorous definition of severe calcification in the ORBIT II trial. The applicant also emphasized that the ORBIT II trial is one of the few FDA-approved single-arm coronary PCI trials in the last two decades, and that the lack of a comparator group does not negate the logic and scientific validity of the trial. Other commenters believed that there is adequate clinical and economic evidence to justify an approval of new technology add-on payments for the DIAMONDBACK® Coronary OAS due to the high-risk and resource intensive treatment that is typical for a patient diagnosed with severely calcified coronary lesions.

Response: We appreciate the commenters' input. However, we do not believe the safety and efficacy endpoints used in the ORBIT II trial represent a substantial clinical improvement over existing atherectomy devices available and accessible to the Medicare population. While we recognize that the DIAMONDBACK® Coronary OAS has met the FDA's standards for safety and effectiveness, the new technology add-on payment policy requires that the technology demonstrate a substantial clinical improvement, which is not inherent in FDA's regulatory process. Moreover, while we agree with the commenters that patients with severely calcified coronary lesions require more resource intensive treatment and are at higher risk of responding poorly to currently available treatments, we also are not convinced that this patient population is not currently being treated with the use of a rotational, directional, or laser atherectomy device that achieves the same or similar therapeutic outcomes as the DIAMONDBACK® Coronary OAS. Because the applicant did not include data to compare the performance of currently available atherectomy devices used in treating patients diagnosed with severely calcified coronary lesions, we remain unable to make a determination as to whether use of the DIAMONDBACK® Coronary OAS results in a substantial clinical improvement over existing and currently available treatment options for the Medicare population.

After consideration of the public comments we received, we have determined that the DIAMONDBACK® Coronary OAS does not meet the criteria for approval of a new technology add-on payment. We remain concerned as to whether the DIAMONDBACK® Coronary OAS meets the newness criteria. Furthermore, we do not believe that the device represents a substantial clinical improvement over existing and currently available treatment options. Therefore, we are not approving new technology add-on payments for this technology for FY 2016.

c. CRESEMBA® (Isavuconazonium)

Astellas Pharma US, Inc. (Astellas) submitted an application for new technology add-on payments for CRESEMBA® (isavuconazonium) for FY 2016. CRESEMBA® is an intravenous and oral broad-spectrum antifungal used for the treatment of adults who have severe invasive and life-threatening fungal infections, including invasive aspergillosis and mucormycosis (zygomycosis).

CRESEMBA® received FDA approval on March 6, 2015. The FDA indication for the use of this product is for the treatment of adults who have been diagnosed with invasive aspergillosis and mucormycosis. Isavuconazonium has two formulations: an intravenous (IV) solution and an oral capsule. The IV formulation of CRESEMBA® is administered at 200 mg while the oral formulation is administered at 100 mg. Dosing is not weight-based. According to the applicant, treatment of patients who have been diagnosed with these types of infection starts with up to 3 days of IV therapy in the inpatient hospital setting followed by daily oral therapy administered for the remainder of the inpatient stay and also the duration of treatment period, which is approximately 13.4 days.

As stated in section II.G.1.a. of the preamble of the proposed rule and this final rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. In the proposed rule, we noted that the applicant had applied for a new ICD–10–PCS procedure code for consideration at the March 18–19, 2015 ICD10–CM/PCS Coordination and Maintenance Committee Meeting. In this final rule, we note that the following two new ICD–10–PCS procedure codes have been established to uniquely identify procedures involving CRESEMBA®: XW03341 (Introduction of isavuconazole anti-infective into peripheral vein, percutaneous approach, new technology group 1); and XW04331 (Introduction of isavuconazole anti-infective into central vein, percutaneous approach, new technology group 1). More information on this request and the approval can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html.*

The applicant maintained that CRESEMBA® meets the newness criterion based on the March 6, 2015 FDA approval of the technology.

CRESEMBA® is part of the category of drugs known as azole antifungal drugs that inhibit the enzyme lanosterol 14 α-demethylase. Inhibiting this enzyme disrupts the process of converting lanosterol to ergosterol and, therefore, depletes the level of ergosterol in the fungal membrane and inhibits fungal growth. Azole antifungal drugs are used to treat patients with fungal infections such as aspergillosis, and other azole

antifungal drugs also used for the treatment of these patients include voriconazole, posaconazole, and itroconazole. The CDC Web site at *http://www.cdc.gov/fungal/diseases/aspergillosis/treatment.html* states that voriconazole is used for the treatment of patients with invasive aspergillosis, but amphotericin B (Amp B) as well as other antifungal drugs can be used if patients cannot take voriconazole or the infection is not responsive to voriconazole. Amphotericin B is the first-line of therapy and the only FDA-approved treatment of patients diagnosed with mucormycosis. Amphotericin B binds with ergosterol, a component of fungal cell membranes, and forms a transmembrane channel that leads to membrane leakage, which is the primary effect leading to fungal cell death. The third class of antifungal drugs is echinocandins; examples in this group are caspofungin, micafungin, and anidulafungin. Echinocandins noncompetitively inhibit beta-1, 3–D-glucan synthase enzyme complex in susceptible fungi to disturb fungal cell glucan synthesis. Beta-glucan destruction prevents resistance against osmotic forces, which leads to cell lysis (*http://www.cdc.gov*).

According to the applicant, echinocandins are effective against aspergillosis. Voriconazole is the recommended treatment for patients diagnosed with invasive aspergillosis. However, amphotericin B and other antifungal drugs may also be used if voriconazole cannot be administered because a patient is suffering from porphyria (a rare inherited blood disorder) or has had an allergic reaction to the drug or the infection is not responding to treatment using voriconazole. In addition, according to the applicant, the efficacy of azole antifungal drugs, such as posaconazole, in treating mucurmycosis is uncertain but has been described in certain situations.

The applicant stated that it is challenging to clinically distinguish the type of antifungal infection a patient may be experiencing. Therefore, the typical treatment of patients exhibiting symptoms of an invasive fungal infection includes both amphotericin B and voriconazole. According to the applicant, for the Medicare population, both drugs are usually administered in combination because it is difficult and time-consuming to delineate the specific type of fungal infections. The applicant noted that these patients are often severely ill and immediate treatment of these symptoms is essential to the effective management of their condition.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24442), we stated we were concerned that CRESEMBA® may not meet the newness criterion because it may be substantially similar to other currently approved antifungal drugs. We refer readers to the FY 2010 LTCH PPS final rule (74 FR 43813 through 43814) for a discussion of our established criteria for evaluating whether a new technology is substantial 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.

In evaluating this technology for substantial similarity, in the proposed rule, we stated that we believe that CRESEMBA® has a similar mechanism of action as the other groups of antifungal drugs available for the treatment of patients diagnosed with serious fungal infections, such as invasive aspergillosis and mucormycosis. As previously noted, voraconazole and itroconazole also are commonly used azole antifungals used to treat patients diagnosed with aspergillosis. The applicant maintained that the availability of the drug in an oral formulation constitutes a different mechanism of action from the current azoles. In the proposed rule, we stated that we disagreed with the applicant's assertion because we believe a different method of administration does not necessarily equate to a different mechanism of action. Although the applicant maintained that this technology is not substantially similar because it is administered orally, the applicant did not describe why it believed a different method of administration constitutes a different mechanism of action. Because CRESEMBA® is part of the category of drugs currently available known as azole antifungal drugs that inhibit the enzyme lanosterol 14 α-demethylase, it appears that the mechanism of action is not different, but that merely the method of administration differs.

With respect to the second criterion for determining substantial similarity, we stated in the proposed rule that we believe that the use of CRESEMBA® is inclusive of the current treatment options available to Medicare beneficiaries and is also currently described (although not specifically) by established procedure codes that identify similar technologies, specifically other antifungal drugs that also are used in the treatment of patients diagnosed with similar fungal infections. The use of antifungal drugs is considered a nonoperating room procedure, which does not impact the MS–DRG assignment of a patient case. Therefore, the use of CRESEMBA® would not impact the MS–DRG assignment of a particular case. Furthermore, the FDA approval for the technology is indicated for use in the treatment of the same or similar type of disease and the same or similar patient population. According to the applicant, CRESEMBA® is used in conjugation with other treatments, and this is reflected in its analysis for the new technology cost criterion. In the proposed rule, we stated our concern that this technology is administered with the other currently available treatments and, therefore, cannot be considered an alternative treatment option. Therefore, we stated that we believe that CRESEMBA® may be considered substantially similar to other available treatments and could not be considered to be ''new'' for purposes of new technology add-on payments.

We invited public comments on if, and how, CRESEMBA® meets the newness criterion and our concerns regarding how it is similar to other treatments for serious fungal infections.

Comment: One commenter (the applicant and manufacturer of CRESEMBA®) submitted comments to further support its assertion and address our concerns that CRESEMBA® meets the newness criterion. The applicant stated that although the active moiety contained in CRESEMBA® has a similar mechanism of action as the other groups of antifungal drugs available for the treatment of patients diagnosed with serious fungal infections, such as invasive aspergillosis and mucuromycosis, CRESEMBA® contains a water soluble prodrug specifically developed to facilitate the systemic delivery of the active moiety. The applicant pointed out that the technology allows intravenous administration without the need for nephrotoxic excipients, such as cyclodextrins, that are present in other antifungals, which are restricted from use in the treatment of patients diagnosed with renal impairment.[16] The applicant further noted that CRESEMBA® administered

[16] Ader *et al*, 2009; Girmenia, 2009.

intravenously can be used in patients diagnosed with renal impairment, and dose adjustments are not necessary or recommended for the treatment of elderly patients or patients diagnosed with renal impairments.

The applicant further stated that other existing treatments for invasive mold infections have limitations due either to the potential for toxicity, or restrictions on its use in the treatment of certain at-risk patient populations. The commenter noted that, although the liposomal preparation of amphotericin B has reduced the potential for nephrotoxicity, it does not eliminate it completely. According to the applicant, amphotericin B is nephrotoxic when administered with calcineurin inhibitors and also requires intravenous administration, which may complicate long-term administration. The applicant reiterated that cyclodextrins used in the intravenous preparation of posaconazole, itraconazole and voriconazole exhibit additional nephrotoxicity and, therefore, its uses in the treatment of patients diagnosed with renal impairment are restricted.[17] Therefore, the applicant believed that there is an urgent need for potent and safe antifungal agents that can be administered both orally and intravenously without increased potential for nephrotoxicity.

The applicant also clarified that CRESEMBA® does not need to be administered in conjugation with other currently available treatments. The applicant stated that the results of its phase III studies demonstrated the efficacy of the CRESEMBA® technology as a singular treatment for invasive mold infections. In addition, the applicant stated that it recognized that CRESEMBA® has some attributes that are similar to other azoles antifungals. However, it believed that CRESEMBA® offers a needed alternative therapy for the treatment of patients diagnosed with invasive aspergillosis (IA) and mucuromycosis (IM), given that currently approved therapies for the treatment of IA and IM are limited by: (1) Pharmacokinetic challenges and toxicity, as noted with voriconazole; and (2) sub-optimal efficacy in high-risk patients, as noted with amphotericin B. The applicant stated that these two characteristics make these therapies often unusable in the treatment of patients most likely to later suffer from a diagnosis of IA and IM (for example, immunocompromised patients), and mortality rates remain high for both diseases. The applicant further stated that patients diagnosed with progressive IA or who are intolerant of voriconazole have few viable options, and there are currently no other approved primary treatments for patients diagnosed with IM except amphotericin B. The applicant believed that CRESEMBA® is an alternative treatment option because patients who cannot tolerate other existing therapies can be treated with CRESEMBA®; otherwise, no other treatment option would be available.

The applicant asserted that data from studies of both the oral and IV formulations have shown that CRESEMBA® has a more predictable pharmacokinetic/pharmacodynamic profile compared to voriconazole. The applicant further indicated that CRESEMBA® has moderate pharmacokinetic variability, which limits the risk of sub-therapeutic or supra-therapeutic exposure, while the variability of voriconazole pharmacokinetics is high. According to the applicant, the pharmacokinetics of CRESEMBA® include: Linear and dose-proportional effects following both oral and IV administration; a long half-life enabling once daily maintenance dosing; oral bioavailability of 98 percent; the absence of food orgastric pH effects; and the option to be administered via both routes of administration under fed or fasting conditions irrespective of the use of drugs that increase gastric pH. Therefore, the applicant believed that a more manageable drug-drug interaction profile was observed with respect to the CRESEMBA® technology compared to other mold-active azoles antifungals.

Response: We appreciate the applicant's additional input and information in support of the application. We recognize that the CRESEMBA® prodrug was specifically developed to facilitate the systemic delivery of the active moiety and reduces the risk of nephrotoxicity relative to other azole antifungals. However, despite the lack of presence of nephrotoxic cyclodextrins, we continue to believe that the CRESEMBA® uses the same mechanism of action as other azole antifungals because they both inhibit the enzyme lanosterol 14 *a*-demethylase.

In addition, we continue to believe that the CRESEMBA® technology is substantially similar to the current treatment options available to Medicare beneficiaries that are also currently described (although not specifically) by established procedure codes that identify the use of these similar technologies, specifically other antifungal drugs that also are used in the treatment of patients diagnosed with similar fungal infections. As the applicant stated, while the use of amphotericin B may not be an ideal treatment option for some patients because it has many adverse side effects, we disagree with the applicant that CRESEMBA® offers an alternative treatment option instead of amphotericin B for patients who cannot tolerate other existing therapies and would otherwise have no other treatment option because amphotericin B and other antifungal drugs can also be effective and used as an option to treat patients diagnosed with IM. Therefore, we believe that, although CRESEMBA® can be effectively administered without other antifungal drugs, the technology would be used to treat the same or similar type of disease and the same or similar patient population as other antifungal drugs.

After consideration of the public comment we received, we believe that the CRESEMBA® technology is substantially similar to other azole antifungal drugs because it meets all three of the criteria identified above and, therefore, does not meet the newness criterion.

As we discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24442 and 24443), to demonstrate that the technology meets the cost criterion, the applicant performed two analyses. The applicant searched claims in the FY 2013 MedPAR file (across all MS–DRGs) for any case reporting a principal or secondary diagnosis of aspergillosis (ICD–9–CM diagnosis code 117.3), zygomycosis [phycomycosis or mucormycosis] (ICD–9–CM diagnosis code 117.7), or pneumonia in aspergillosis (ICD–9–CM diagnosis code 484.6). The applicant excluded any case that was treated at a hospital that is not paid under the IPPS, as well as any case where Medicare fee-for-service was not the primary payer. The applicant calculated the standardized charge for each eligible case and then inflated the standardized charge by 10.4427 percent using the same inflation factor used by CMS to update the FY 2015 outlier threshold (79 FR 50379). The applicant assumed that the average length of stay for all eligible cases was 13.4 days based on its analysis. To determine the charges for the drug, the applicant assumed 13.4 days of therapy. According to the applicant, dosages of isavuconazole for a patient vary based on the day of therapy, but do not vary based on the patient's weight. For the first and second day of therapy, the patient would be administered a loading dose of 200 milligrams (mg) every 8 hours. For each subsequent day of therapy, the patient would be

[17] Ibid.

administered a maintenance dose of 200 mg per day.

For the first analysis, which was based on 100 percent of all MS–DRGs, the applicant identified a total of 5,984 cases with at least one of the three ICD–9–CM codes (aspergillosis (ICD–9–CM diagnosis code 117.3), zygomycosis [phycomycosis or mucormycosis] (ICD–9–CM diagnosis code 117.7), or pneumonia in aspergillosis (ICD–9–CM diagnosis code 484.6)) across a total of 333 MS–DRGs. The applicant's rationale for using all the MS–DRGs was that it believed any patient diagnosed with either invasive aspergillosis or invasive mucormycosis (zygomycosis) could be eligible for treatment using isavuconazonium, regardless of the MS–DRG assignment. The applicant identified the average case-weighted threshold amounts for these 333 MS–DRGs as $72,186 using Table 10 from the FY 2015 IPPS/LTCH PPS final rule. The applicant did not remove charges for the other specific technologies from the average case-weighted standardized charge per case. The applicant's rationale for not removing these charges was that the patients would be administrated isavuconazonium in combination with the other currently approved antifungal drugs as an effective treatment plan. The applicant computed a final inflated average case-weighted standardized charge per case of $151,450. Because this average case-weighted standardized charge per case exceeded the average case-weighted threshold amount from the FY 2015 Table 10, the applicant maintained that CRESEMBA® meets the cost criterion using this first analysis.

For its second analysis, the applicant analyzed 39 MS–DRGs that accounted for the top 75 cases of patients eligible for treatment using isavuconazonium; this was a subset of 4,510 cases. Using a methodology similar to the one used in its first analysis, the applicant computed the final inflated average case-weighted standardized charge per case of $159,622. The applicant identified an average case-weighted threshold amount for the 39 MS–DRGs of $74,366 using Table 10 from the FY2015 IPPS/LTCH PPS final rule. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in the FY 2015 Table 10, the applicant maintained that CRESEMBA® meets the cost criterion using this second analysis.

In the proposed rule, we stated we were concerned that the applicant did not remove any charges for the other antifungal drugs used during treatments (that is, the other component of the combination) because the applicant maintained that it would most likely be necessary for patients who are treated using CRESEMBA® to also continue treatment using the other antifungal drugs or medications in order to achieve successful treatment due to the severity of their symptoms. We believe that the applicant should have removed the charges for the other antifungal drugs used for treatments. We also noted that the applicant did not provide information to substantiate its assertion that the charges for these cases would not be reduced because of the severity of illness among the patients. The applicant inferred that patients treated using CRESEMBA® would be dependent upon the simultaneous and combined use of the other existing therapies to achieve successful treatment. Therefore, we stated our concern about the possibility of drug toxicity, poly pharmacy, and drug-to-drug interactions, especially among the Medicare population.

We invited public comment on whether CRESEMBA® meets the cost criterion, specifically with regard to our concerns regarding the applicant's analyses and methodology.

Comment: To address CMS' concerns stated in the proposed rule, the applicant submitted additional information that included the results from conducted sensitivity analyses to determine whether the cost of the cases included in its cost analysis presented in the proposed rule would have continued to exceed the cost threshold for the respective MS–DRGs after removing the submitted charges for other drugs. Using a methodology similar to the methodology used in the previous cost analyses as presented in the proposed rule, the applicant conducted three subsequent analyses that removed 18.3 percent, 41.0 percent, and 100 percent of charges associated with other drugs. The applicant reported that the average case-weighted threshold amount for the respective MS–DRGs remained at $72,186. Under each analysis, the average case-weighted standardized charges per cases were $145,260, $137,641, and $117,838 respectively. Because the average case-weighted standardized charge per case for each scenario exceeded the average case-weighted threshold amount for the respective MS–DRGs ($72,186), the applicant maintained that the CRESEMBA® meets the cost criterion based on the results of its new analysis.

Response: We appreciate the applicant's additional input and information. After consideration of the subsequent analysis presented by the applicant and its results, we believe that the CRESEMBA® meets the cost criterion.

As we discussed in the proposed rule, with regard to substantial clinical improvement, the applicant stated that CRESEMBA® represents a substantial clinical improvement over existing therapies for patients diagnosed with invasive aspergillosis and mucormycosis based on its potentially improved efficacy profile, potentially improved safety profile, more favorable pharmacokinetic profile, and improved method of administration. The applicant discussed the unmet medical need for alternative treatment options for patients diagnosed with invasive aspergillosis and mucormycosis. Current treatments have limitations related to safety, side effects, and efficacy.[18] [19] The applicant provided information regarding its SECURE study, where the primary endpoint of all-cause mortality through day 42 showed that CRESEMBA® demonstrated noninferiority to voriconazole. The primary endpoint of all-cause mortality through day 42 in the intent-to-treat population (ITT, N=516) was 18.6 percent in the isavuconazonium treatment group and 20.2 percent in the voriconazole group. However, according to the applicant, the overall safety profile for CRESEMBA® demonstrated similar rates of mortality and nonfatal adverse events as the comparator, voriconazole. The applicant also shared information from other clinical trials. One of these clinical trials that studied the treatment of patients diagnosed with invasive aspergillosis showed treatment-emergent adverse reactions occurred in 96 percent and 99 percent of patients receiving the CRESEMBA® and voriconazole. In the proposed rule, we stated that the adverse reactions associated with the use of CRESEMBA® and voriconazole appear to be similar.

Comment: In response to our concerns, the applicant noted that patients being treated with CRESEMBA® had a reduced number of treatment-related discontinuations over existing therapies. The applicant stated that the treatment-emergent adverse events (TEAEs) were reported in 96.1 percent of patients who received treatment using the CRESEMBA® technology and 98.5 percent of patients who received treatment using voriconazole. The applicant further stated that the five most common events

[18] Lin SJ, Schranz J, Teutsch SM.: Aspergillosis case-fatality rate: systematic review of the literature. ClinInfect Dis. 2001;32:358-66.

[19] Greenberg RN, Scott LJ, Vaughn HH, Ribes JA.: Zygomycosis (mucormycosis): emerging clinical importance and new treatments. Curr Opin Infect Dis. 2004;17:517–25.

that occurred in ≥5 percent of the patients in either group were nausea, vomiting, diarrhea, pyrexia, and hypokalemia, and the most frequent adverse events by system organ class were gastrointestinal disorders (67.7 percent for patients treated using CRESEMBA,® 69.5 percent for patients treated using voriconazole), and infections/infestations (59.1 percent for patients treated using CRESEMBA,® 61.0 percent for patients treated using voriconazole). The applicant also noted that the results indicated the following TEAEs were significantly less common with the group of patients treated using CRESEMBA® compared to the group of patients treated using voriconazole: Skin and subcutaneous tissue disorders (33.5 percent for the group of patients treated with CRESEMBA,® 42.5 percent for the group of patients treated using voriconazole; p = 0.037), eye disorders (15.2 percent for the group of patients treated using CRESEMBA,® 26.6 percent for the group of the patients treated using voriconazole; p = 0.002), and hepatobiliary disorders (CRESEMBA® 8.9 percent, voriconazole 16.2 percent; p = 0.016). The applicant believed that the differences between the efficacy and effectiveness of the CRESEMBA® compared to voriconazole as a result of the overall analysis of TEAEs and serious TEAEs were consistent with those of the subgroup analysis by age categories, gender, race, ethnicity, geographical region, receipt of allogeneic transplantation, active malignancy status, and neutropenia at baseline. The applicant stated that no clinically relevant trends were observed with other safety parameters, including laboratory parameters and ECG during the 84-day treatment period.

Response: We appreciate the additional information presented by the applicant in response to our concerns. While we recognize that CRESEMBA® meets FDA standards for safety and effectiveness, demonstration of a substantial clinical improvement over existing technologies available to Medicare beneficiaries is not necessarily inherent in the FDA's regulatory requirement for the technology. We believe that the data presented by the applicant to support a substantial clinical improvement based on the demonstration of reduced TEAEs did not show results demonstrating significant differences regarding the analysis' comparables. While we acknowledge that, in the setting of similar overall safety profiles, the discontinuation rates are reduced with the use of the CRESEMBA® technology when compared to use of voriconzole, we are unsure if the noted differences in the overall safety profiles demonstrate statistical significance.

In the proposed rule, we also stated that we were concerned that the applicant did not conduct the clinical trials evaluating head-to-head comparisons to alternative therapies such as amphotericin B. Currently, amphotericin B is the only FDA-approved drug for the treatment of mucormycosis, which also can be used to treat aspergillosis. The applicant's description of the technology was based on peer reviewed literature, which may be considered historical data.

Comment: The applicant also presented with its comments findings from the Fungiscope Registry database to demonstrate the results of head-to-head comparisons between the efficacy of effectiveness of the CRESEMBA® and other alternative therapies such as amphotericin B. The applicant stated that, in a matched-case control analysis, crude mortality through day 42 in patients who received treatment using CRESEMBA® as primary therapy was 33.3 percent relative to 39.4 percent in patients who received amphotericin-based treatment as primary therapy from matched controls, while the overall mortality rate (37.8 percent) for patients treated using CRESEMBA® was similar to the mortality rate for patients treated with amphotericin B as reported in the literature (37.8 percent).

Response: We appreciate the information included in the applicant's comment in response to our concern. However, we believe that the crude mortality rates for both controls were similar, and the noted differences do not appear to be statistically significant.

With regard to improved efficacy, the applicant made several assertions in its application that we discussed in the proposed rule (80 FR 24443 through 24444). The applicant maintained that the use of CRESEMBA® can potentially decrease the rate of subsequent diagnostic or therapeutic interventions. According to the applicant, the technology lacks the adverse side effects of nephrotoxicity associated with amphotericin B.[20] However, in the proposed rule we stated that the results of the study reported by the applicant did not reflect this.

Specifically, the applicant believed that CRESEMBA® has positive activity against a broad range of fungi, including those resistant to other agents, thereby potentially decreasing subsequent therapeutic interventions.[21] However, the applicant stated that the referenced literature indicates that further in-vivo studies are required in order to confirm the efficacy for treatment of severe infections caused by these fungi in immunocompromised patients. According to the applicant, CRESEMBA® is used to treat immunocompromised patients who are severely ill. The applicant also stated that CRESEMBA® can be used to treat patients diagnosed with invasive fungal infections before the pathogen has been identified, thereby potentially decreasing subsequent diagnostic and therapeutic interventions.[22] The applicant maintained that the use of CRESEMBA® decreases the number of future hospitalizations or physician visits. We stated in the proposed rule (80 FR 24444) our concern that the applicant did not provide data to support this determination. One of the applicant's studies, SECURE, which was a global, Phase 3, multicenter, randomized, double-blind, parallel group, noninferiority trial that evaluated CRESEMBA® versus voriconazole for the primary treatment of patients with invasive fungal disease (IFDs) caused by aspergillus spp. and other filamentous fungi was discussed by the applicant in its application. The results of the study were presented in a paper stating that the length of stay for patients hospitalized with renal impairment was statistically significantly shorter in the treatment of patients in the CRESEMBA® arm (9 days) compared with patients treated with voriconazole in the control arm. According to the applicant, patients treated with CRESEMBA® showed shorter hospital length of stay compared to those treated with voriconazole in the overall study population. Subgroup analyses of patients who were aged 65 years and older and patients with a BMI equal to or greater than 30 kg/m^2 also had shorter, but not statistically significant, differences in length of stay when treated with isavuconazonale compared to voriconazole. The paper on the study revealed concerns about the small sample size in the subgroup (n=516) and that the differences were not statistically significant.[23]

[20] Walsh TJ, Anaissie EJ, Denning DW, Herbrecht R, Kontoyiannis DP, Marr KA, *et al.*: Treatment of aspergillosis: Clinical practice guidelines of the Infectious Diseases Society of America. Clin Infect Dis. 2008;46:327–60.

[21] González GM.: Med Mycol. 2009 Feb;47(1):71–6. doi:10.1080/13693780802562969. Epub 2008 Dec 18. PMID: 19101837 [PubMed—indexed for MEDLINE].

[22] Kontoyiannis DP, Lewis RE.: How I treat mucormycosis. Blood. 2011;118:1216–24.

[23] Khandelwal N, Franks B, Shi F, Spalding J, Azie N. Health Economic Outcome Analysis of Patients Randomized in the SECURE Phase 3 Trial

Continued

With regard to improved safety and a more favorable pharmacokinetic profile, the applicant made several assertions which we discussed in the proposed rule (80 FR 24444). The applicant asserted that CRESEMBA® has the potential for simpler and more predictable dosing based on improved pharmacokinetics compared with other azole antifungal drugs, but the applicant did not provide data to substantiate this assertion.

Comment: The applicant provided the following information in its comment with regard to CRESEMBA's pharmacokinetic profile and predictable dosing. According to the applicant, based on data from the development of CRESEMBA® and the prescribing information, CRESEMBA® does not require therapeutic drug monitoring (TDM) compared to voricanozole, which requires TDM due to liver disease, age and genetic polymorphisim of the cytochrome CYP2C19. The applicant noted that, for CRESEMBA®, no dose adjustment is required for the following: Age, gender, and race; mild, moderate, and severe renal impairment including patients with ESRD; mild to moderate hepatic impairment patients. The applicant included additional information from the Secure Phase III trial and other clinical studies [24] [25] to substantiate that CRESEMBA® has the potential for simpler and more predictable dosing based on improved pharmacokinetics compared with other azole antifungal drugs.

Response: We appreciate the additional information provided by the applicant. We note that, with regard to the pharmacokinetic profile, based on the information provided by the applicant, CRESEMBA® appears to have a favorable profile, but the data relating to a comparison of rates for TEAEs between CRESEMBA® and voriconazole show that the rates are the same. In addition, while the applicant stated that CRESEMBA® does not require therapeutic drug monitoring (TDM) as compared to voricanozole, which does require TDM, we note that the FDA has indicated in the product labeling that serious hepatic reactions have been reported regarding the effects of the use of the CRESEMBA® and the FDA has recommended that treatment include the evaluation of liver related laboratory tests at the start and during the course of treatment using the CRESEMBA® therapy (similar to FDA indications for voricanozole).

As we discussed in the proposed rule, the applicant also asserted that CRESEMBA® has a lower drug-drug interaction potential than voriconazole or itraconazole, but did not provide data to substantiate this assertion. Furthermore, the applicant maintained that CRESEMBA® can be safely used in treating patients with renal impairment, whereas currently available treatments can harm the kidneys.[26] In the paper accompanying the application, the applicant discussed aspergillosis and the various treatment options available and the advantages of voriconazole over deoxycholate amphotericin B (D–AMB) as primary treatment for patients with invasive aspergillosis. In the proposed rule, we stated we were concerned that these results were not communicated in the resulting data provided by the applicant that were obtained from the trials (80 FR 24444).

Comment: The applicant stated in its comment that based on the Phase 3 trials, 79 of 403 patients had an estimated glomerular filtration rate (GFR) less than 60 mL/min/1.73 m^2. The applicant also provided data from a phase one study, which evaluated the pharmacokinetics in patients diagnosed with mild, moderate, and severe renal dysfunction relative to the pharmacokinetics in healthy patients with normal renal function.[27] The applicant noted that CRESEMBA® area under the curve 72 (AUC72) in ESRD patients is similar to the AUC72 in healthy controls due to the hemoconcentration because CRESEMBA® is highly protein bound (>99 percent) and not dialyzable.

The applicant presented the results from an analysis of a pooled subgroup from its previously stated studies (SECURE and VITAL), which evaluated the effectiveness of CRESEMBA® in patients diagnosed with and without renal impairment, as defined as eGFR < 60 mL/min/1.73 m^2. The end points measured were all cause mortality at day 42 and day 84 and DRC assessed overall response at end of treatment (EOT). At the end of day 42, the mortality rates for the patients diagnosed with renal impairment versus patient who do not suffer from renal impaired was 12.9 percent versus 18.8 percent. At the end of day 84, the mortality rates for the patients diagnosed with renal impairment versus patients who do not suffer renal impairment was 25.8 percent versus 28.6 percent. All-cause mortality on Day 42 and Day 84, and DRC-assessed overall response at EOT were comparable between patient groups (32 percent versus 36 percent). The applicant stated that the results of this pooled analysis demonstrated that CRESEMBA® was efficacious in patients diagnosed with renal impairment enrolled in the SECURE and VITAL trials and supports the Phase 1 trial findings that dose adjustments are not required for patients diagnosed with renal impairment treated using the CRESEMBA®.

Response: We appreciate the additional information provided in the applicant's comment in response to our concerns, and we have considered these findings in our final review.

In the proposed rule, we also stated that we were concerned that the applicant did not provide a rationale for its assertion that the use of CRESEMBA® represents a substantial clinical improvement for Medicare beneficiaries because of ''simpler and more predictable dosing'' nor did the applicant provide additional information and data regarding drug-to-drug interactions and nephrotoxicity (80 FR 24444).

In addition, the applicant maintained that the technology has an improved method of administration compared to current treatment alternatives. Specifically, the applicant asserted that the availability of this technology as an oral formulation is an improvement compared to other existing treatments, which are solely administered intravenously. In the proposed rule, we stated that we were concerned about the applicant's assertion because other currently approved and available antifungal drugs, such as voriconazole (tablets, oral suspension, or intravenous administration), itraconazole (capsules, oral solution, or parenteral solution), and posaconazole (oral suspension or parenteral solution), also can be administered orally as well as parenteral for patients diagnosed with these types of fungal infections. In addition, we are aware that intravenous administration of antifungal drugs may be necessary because patients diagnosed with invasive aspergillosis and mucuromycosis and treated as inpatients are often severely ill and may

Comparing Isavuconazole to Voriconazole for Primary Treatment of Invasive fungal Disease Caused by Aspsergillus Species or Other Filamentous Fungi.

[24] CRESEMBA® [package insert]. Northbrook, IL: Astellas, Inc.

[25] Desai A, Kovanda L, Kowalski D, Lu Q, Townsend R. Isavuconazole (ISA) Population Pharmacokinetic Modeling from Phase 1 and Phase 3 Clinical Trials and Target Attainment Analysis. Proceedings of the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy Washington, DC [Poster#A–697]. 2014.

[26] Walsh TJ, Anaissie EJ, Denning DW, Herbrecht R, Kontoyiannis DP, Marr KA, *et al.* Treatment of aspergillosis: Clinical practice guidelines of the Infectious Diseases Society of America. Clin Infect Dis. 2008;46:327–60.

[27] Astellas. CRESEMBA®. Clinical Study Report No. 9766–CL–0018. Data on File.

not be able to tolerate any food or medications orally.

Comment: The applicant responded to CMS' concerns expressed in the proposed rule by presenting information that highlighted the following results based on data from the clinical studies: Both the oral and IV formulations have shown that CRESEMBA® has a more predictable pharmacokinetic/pharmacodynamic profile when compared to voriconazole; CRESEMBA® has moderate pharmacokinetic variability, limiting the risk of sub-therapeutic or supra-therapeutic exposure, while the variability of voriconazole pharmacokinetics is high; IV CRESEMBA® can be used in patients diagnosed with renal impairment as the IV formulation of CRESEMBA® does not include cyclodextrins.

The applicant further stated that the Pharmacokinetics (PK) study in patients diagnosed with renal impairment demonstrated exposures that support the label that no dose adjustments are recommended in patients who are elderly or renally impaired and no dose adjustment is needed in patients diagnosed with mild, moderate, or severe renal impairment, including those patients with ESRD. The applicant noted that outcomes in the renal impaired patients were comparable to the non-renal impaired.

According to the applicant, a more manageable drug-drug interaction profile was observed with CRESEMBA® than with other mold-active azoles. The applicant explained the following with regard to CRESEMBA®: It is a sensitive substrate of CYP3A (5-fold increase in isavuconazole AUC with concomitant ketoconazole) and a mild-to-moderate inhibitor of CYP3A4 (2-fold increase in midazolam AUC), while voriconazole is a strong inhibitor of CYP3A4 (10-fold increase in midazolam AUC); it is a mild inducer of CYP2B6 (42 percent decrease in bupropion); it does not inhibit or induce CYP1A2, CYP2C9, or CYP2C19 and does not inhibit CYP2A6 or CYP2D6; it is a mild inhibitor of P-gp, OCT1/OCT2 and MATE1; it has no inhibitory effects on sensitive substrates of BCRP, OAT1/OAT2, OATP1B1/OATP1B3, or MATE2-K, but does have mild indirect inhibitory effects on substrates of UGT.

The applicant also stated that CRESEMBA® demonstrated efficacy in the studies of patients diagnosed with IA and IM. The applicant asserted that CRESEMBA® demonstrated the following: Noninferior efficacy compared to voriconazole for the primary endpoint of all-cause mortality through day 42 in IA; comparable results for all-cause mortality were observed across sensitivity analyses, populations, time points and subgroups, further supporting the effectiveness of CRESEMBA®; and activity against several species of Mucorales, which are known to mimic *Aspergillus* infection and have been reported as a cause of breakthrough infection.

The applicant noted that CRESEMBA® had a similar treatment effect to that of amphotericin B compared to untreated controls from the literature for all-cause mortality. The applicant cited a matched-case analysis from a contemporary registry in which similar mortality rates were noted in patients treated with CRESEMBA® and matched control patients treated with amphotericin-based formulations. The applicant also noted that CRESEMBA® activity is supported by data from validated animal models of mucormycosis.

According to the applicant, CRESEMBA® demonstrated the following: A favorable safety profile compared to voriconazole; and fewer CRESEMBA® TEAEs compared to voriconazole such as skin, eye and hepatic adverse events. Finally, the applicant stated that CRESEMBA® is orally bioavailable and has no signal of nephrotoxic effects as associated with amphotericin B.

Response: We appreciate the applicant's additional information submitted in response to our concerns regarding a lack of data for: (1) Head-to-head comparative studies between CRESEMBA® and alternative therapies in the treatment of aspergillosis and invasive mucormycosis (IM); (2) safety in treating patients with renal impairment; and (3) predictable dosing based on improved pharmacokinetics compared with other azole drugs for anti-fungal therapy. We note that in the matched-case control analysis, Study 0103 (Fungiscope Registry) specifically compared CRESEMBA® with amphotericin B in the treatment of IM, and that this study showed for IM patients treated with CRESEMBA® the mortality rate was 33.3 percent (7/21) and for IM patients treated with Amphotericin B the mortality rate was 39.4 percent (3/33). With regard to safety in treating patients with renal impairment, we agree with the applicant that relative to amphotericin B, CRESEMBA® can be a useful alternative for treating patients diagnosed with mucuromycosis with regard to the nephrotoxic side effects associated with amphotericin B. While the applicant believed that CRESEMBA® has the potential for simpler and more predictable dosing based on improved pharmacokinetics compared with other azole drugs, we are concerned that the differences in rates for TEAEs between CRESEMBA® and voriconazole are not statistically significant and, therefore, the favorable pharmacokinetics profile of CRESEMBA® may not represent a substantial clinical improvement over currently available treatments using other azole antifungal drugs.

While amphotericin B has severe side effects, CRESEMBA® is associated with serious hepatic reactions, which requires the evaluation of liver related laboratory tests at the start and during the course of treatment using the CRESEMBA® therapy. In addition, in the Fungiscope Registry referenced by the applicant, we note that the crude mortality rates for CRESEMBA® and amphotericin B were similar.

While we acknowledge that CRESEMBA® reduces some side effects associated with the treatment of invasive antifungal infections, we believe that its outcomes are markedly similar to those accomplished using other azole antifungal drugs currently available to Medicare beneficiaries and proven to be effective in the treatment of these types of diagnoses. Therefore, we do not believe that the CRESEMBA® represents a substantial clinical improvement over existing technologies.

Comment: One commenter did not believe that the CRESEMBA® technology represents substantial clinical improvement over existing technologies.

Response: We agree with the commenter that the technology does not represent a substantial clinical improvement over existing technologies.

After consideration of the public comments we received, for the reasons discussed earlier, we believe that the CRESEMBA® technology is substantially similar to other antifungal drugs used in the effective treatment of patients diagnosed with similar types of conditions that are currently available to Medicare beneficiaries and, therefore, does not meet the newness criterion. Moreover, we do not believe that the technology represents a substantial clinical improvement over existing technologies. Therefore, we are not approving the CRESEMBA® for new technology add-on payments for FY 2016.

d. LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Two manufacturers, CR Bard Inc. and Medtronic, submitted applications for new technology add-on payments for FY

2016 for LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter (LUTONIX®) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (IN.PACT™ Admiral™), respectively. Both of these technologies are drug-coated balloon angioplasty treatments for patients diagnosed with peripheral artery disease (PAD). Typical treatments for patients with PAD include angioplasty, stenting, atherectomy and vascular bypass surgery. PAD most commonly occurs in the femoropopliteal segment of the peripheral arteries, is associated with significant levels of morbidity and impairment in quality of life, and requires treatment to reduce symptoms and prevent or treat ischemic events.[28] Treatment options for symptomatic PAD include noninvasive treatment such as medication and life-style modification (for example, exercise programs, diet, and smoking cessation) and invasive options which include endovascular treatment and surgical bypass. The 2013 American College of Cardiology and American Heart Association (ACC/AHA) guidelines for the management of PAD recommend endovascular therapy as the first-line treatment for femoropopliteal artery lesions in patients suffering from claudication (Class I, Level A recommendation).[29]

The applicants for LUTONIX® and IN.PACT™ Admiral™ stated that, in patients diagnosed with PAD, the femoropopliteal artery is characterized by difficult to treat lesions that can be long and diffuse, in a vessel that is considered the most mechanically stressed artery with a number of dynamic forces that impact the artery including shortening/elongation, torsion, compression and flexion. According to the applicants, the unique challenges of treating disease in the femoropopliteal region in patients with PAD are related to limitations of current endovascular treatment options. PTA and stents have high restenosis rates. In the case of stents the region is often a no stent zone with concerns of stent fracture and limiting future treatment options with permanent implants. Coating of femoral and coronary stents with an antiproliferative drug, such as paclitaxel, is intended to reduce the development of restenosis in the stented segment of the artery.[30] [31]

The applicants stated that the drug-coated balloon catheter is a device-drug combination product comprised of a device component (an over-the-wire balloon catheter) and a drug component (a paclitaxel-urea coating in the case of IN.PACT™ Admiral™ and a paclitaxel-sorbitol for LUTONIX®) on the balloon, intended for the treatment of patients with PAD, specifically superficial femoral artery (SFA) and popliteal artery disease. The device is engineered for two modes of action: The primary mode of action is attributable to the balloon's mechanical dilatation of de novo or restenotic lesions in the vessel; and the secondary mode of action consists of drug delivery and application of paclitaxel to the vessel wall to inhibit the restenosis that is normally associated with the proliferative response to the PTA procedure. Following predilatation with a nondrug-coated PTA balloon, the interventionalist selects a drug-coated balloon with diameter of 100 percent of reference vessel diameter (RVD) and length sufficient to treat 5mm proximal and distal to the target lesion and predilated segment (including overlap of multiple balloons). The interventionalist inflates the drug-coated balloon for a minimum inflation time of 30 seconds for delivery of paclitaxel, and keeps the balloon inflated for as long as necessary to achieve a satisfactory procedural result, which is the standard of care for all balloon angioplasties.

According to both applicants, LUTONIX® and IN.PACT™ Admiral™ are the first drug coated balloons that can be used for treatment of patients who are diagnosed with PAD. As we stated in the proposed rule, because cases eligible for the two devices would group to the same MS–DRGs and we believe that these devices are substantially similar to each other (that is, they 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 believe that it is appropriate to evaluate both technologies as one application for new technology add-on payment under the IPPS. The applicants submitted separate cost and clinical data, and we reviewed and discuss each set of data separately. However, we are making one determination regarding new technology add-on payments that will apply to both devices. 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 that we believe that continuing our current practice of extending a new technology add-on payment 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 from having to submit separate new technology 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 these substantially similar technologies had been 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, we believe it is appropriate to consider both sets of cost data and clinical data in making a determination because we do not believe that it is possible to choose one set of data over another set of data in an objective manner.

CR Bard, Inc. received FDA approval for LUTONIX® on October 9, 2014. Commercial sales in the U.S. market began on October 10, 2014. Medtronic received FDA approval for IN.PACT™ Admiral™ on December 30, 2014. Commercial sales in the U.S. market began on January 29, 2015.

As stated in section II.G.1.a. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule and this final rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. In the proposed rule, we stated that the applicants applied for a

[28] Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwalder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U.: Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. N Engl J Med 2008; 358: 689–99.

[29] Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, DeMets D, Guyton RA, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Sellke FW, Shen WK.: Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013; 61:1555–70. Available at: *http://dx.doi.org/10.1016/j.jacc.2013.01.004*.

[30] Owens, CD.: Drug eluting balloon overview: technology and therapy. Presented at LINC 2011, Leipzig, Germany.

[31] Scheller B.: Opportunities and limitations of drug-coated balloon in interventional therapies. Herz 2011;36:232–40.

new ICD–10–PCS procedure code for consideration at the March 18–19, 2015 ICD–10–CM/PCS Coordination and Maintenance Committee Meeting. In this final rule, we note that new ICD–10–PCS procedure codes (listed in the chart below) which uniquely identify procedures involving the LUTONIX® and Medtronic drug coated balloons have been established.

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.

More information on the request for and the approval of these codes can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html* and the FY 2016 New ICD–10–PCS Codes can be found at the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*.

As we discussed in the proposed rule, the approval of new technology add-on payments extends to all technologies that are substantially similar. Moreover, as discussed, we believe that applications for substantially similar technologies should be evaluated in a manner that avoids, among other things, having to compare the merits of competing technologies on the basis of substantial clinical improvement. If we receive applications for substantially similar technologies in different years, we would apply the first determination to any subsequent applications for substantially similar technologies. Because, in this case, two substantially similar technologies have applied for a new technology add-on payment for the same Federal fiscal year, we believe it is consistent with our policy to make one determination using all of the information submitted for the technologies rather than choosing one set of information to consider and not considering the other set of information.

In accordance with our policy, we stated in the proposed rule 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 in the proposed rule that if approved for new technology add-on payments, we believe that the beginning of the newness period would be October 10, 2014.

In the proposed rule we did not articulate any concerns regarding whether this technology meets the newness criterion, but we invited public comments on whether these two technologies meet the newness criterion. We did not receive any public comments concerning whether the technologies meet the newness criterion. Therefore, based on the information provided by the applicants, we believe that both LUTONIX® and IN.PACT™ Admiral™ DCBs meet the newness criterion.

As we stated above, each applicant submitted separate analyses regarding the cost criterion for each of their devices and both applicants maintained

that their device meets the cost criterion. As we did in the proposed rule, we summarize each analysis below.

With regard to the LUTONIX®, to demonstrate that the technology meets the cost criterion, the applicant performed three different analyses. The applicant first searched the FY 2013 MedPAR data file that was used for the recalibration of the FY 2015 MS–DRG relative payment weights in the FY 2015 IPPS/LTCH PPS final rule. The applicant applied the standard trims that CMS used when selecting cases for IPPS rate recalibration as described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49911). In other words, the applicant included cases from IPPS hospitals and Maryland hospitals and excluded cases paid by Medicare Advantage plans, cases from hospitals that did not submit charges in a sufficiently broad range of revenue centers, and statistical outlier cases as described in the FY 2015 IPPS/LTCH PPS final rule. The applicant then searched for all claims reporting ICD–9–CM procedure code 39.50 (Angioplasty of other non-coronary vessel(s)) and also reporting at least one of the following seven ICD–9–CM diagnosis codes (440.20 (Atherosclerosis of native arteries of the extremities, unspecified), 440.21 (Atherosclerosis of native arteries of the extremities with intermittent claudication), 440.22 (Atherosclerosis of native arteries of the extremities with rest pain), 440.23 (Atherosclerosis of native arteries of the extremities with ulceration), 440.24 (Atherosclerosis of native arteries of the extremities with gangrene), 440.29 (Other atherosclerosis of native arteries of the extremities), and 443.9 (Peripheral vascular disease, unspecified indicating peripheral artery disease). The applicant excluded all claims that reported any ICD–9–CM procedure codes involving a stent. A total of 23,157 cases reporting peripheral angioplasty were identified. Of these 23,157 cases, MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC and without CC/MCC, respectively) accounted for 65 percent of cases; MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively), MS–DRGs 239 and 240 (Amputation for Circulatory System Disorders Except Upper Limb and Toe with MCC and with CC, respectively), and MS–DRG 853 (Infectious and Parasitic Diseases with Operating Room Procedure with MCC) accounted for 17 percent of cases (among these, peripheral angioplasty was secondary to some other circulation-related procedure: A major cardiovascular procedure (MS–DRGs 237 and 238), amputation due to poor circulation (MS–DRGs 239 and 240), or (typically) amputation with sepsis (MS–DRG 853)). The remaining 18 percent of cases were spread across a large number of other MS–DRGs. Next, the applicant obtained the average case-weighted charge per case based on the distribution of cases by MS–DRG and then identified the average case-weighted threshold for the three MS–DRG groupings from the threshold amounts in Table 10 of the FY 2015 IPPS/LTCH PPS final rule. The applicant then calculated the unadjusted (unstandardized) average case-weighted charge per case for all MS–DRGs. According to the applicant, charges were not removed for any prior technology. To estimate the charge for the new technology, the applicant divided the projected cost per patient by the national average CCR for supplies (0.292) in the FY 2015 IPPS/LTCH PPS final rule, to arrive at the average case-weighted standardized charges per case. The average case-weighted standardized charges per case for the three primary MS–DRGs 252–254 group (65 percent), the five additional MS–DRGs 237–240 and MS–DRG 853 group (17 percent), and the other MS–DRGs (18 percent) were $69,243, $81,156, and $95,138, respectively. The applicant then inflated the average standardized case-weighted charges per case from FY 2013 to FY 2015 using the 2-year inflation factor of 10.44 percent specified in the FY 2015 IPPS/LTCH PPS final rule and added charges related to the new technology to the average case-weighted standardized charges per case, although the applicant indicated that it was not clear on the need to include an inflation factor. The final inflated average case-weighted standardized charges per case for the three primary MS–DRG groups (65 percent), the five additional MS–DRG groups (17 percent), and across other MS–DRGs (18 percent) were $85,386, $98,543, and $104,052, respectively. Because the final inflated average case-weighted standardized charge amounts exceed the corresponding average case-weighted threshold amounts of $69,594, $74,449, and $75,215, respectively, using the FY 2015 IPPS Table 10, the applicant stated that LUTONIX® meets the cost criterion for new technology add-on payments.

With regard to the IN.PACT™ Admiral™, to demonstrate that the technology meets the cost criterion, the applicant performed two different analyses. The applicant believed that a case involving an angioplasty procedure that used the IN.PACT™ Admiral™ drug-coated balloon catheter would map to the same MS–DRGs as a case involving a plain balloon angioplasty procedure, MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively). The applicant first searched the FY 2013 MedPAR claims data that were used for the recalibration of the FY 2015 MS–DRG relative payment weights in the FY 2015 IPPS/LTCH PPS final rule. The data in this file included discharges occurring on October 1, 2012 through September 30, 2013. The applicant excluded claims for all discharges for Medicare beneficiaries enrolled in a Medicare Advantage plan. The applicant also limited claims to those hospitals that were included in the FY 2013 IPPS Final Rule Impact File. In addition, the applicant removed claims in accordance with the trims specified in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53326) that were used to recalibrate the MS–DRG relative payment weights. The applicant then searched for all claims reporting ICD–9–CM procedure code 39.50 (Angioplasty of other non-coronary vessel(s)) in combination with claims reporting at least one of the following seven ICD–9–CM diagnosis codes (440.20 through 440.24, 440.29, and 443.9) indicating peripheral artery disease. The applicant excluded all claims that reported any ICD–9–CM procedure codes for stent implantation. The applicant believed that excluding all cases reporting stenting procedures would potentially underestimate the average charges for cases reporting peripheral angioplasty. A total of 23,157 cases involving peripheral angioplasty procedures were identified. Of these 23,157 cases, a majority (65 percent; 15,040 cases) mapped to one of the 3 primary MS–DRGs, MS–DRGs 252, 253, or 254. The remaining 35 percent of the cases (8,117) were assigned to a number of MS–DRGs other than the 3 primary MS–DRGs. Next, the applicant determined the distribution of cases by MS–DRG and the case-weighted threshold amounts from Table 10 in the FY 2015 IPPS/LTCH PPS final rule, for both the primary MS–DRG group and the total MS–DRG group. The applicant began by calculating the unadjusted (unstandardized) case-weighted average charge per case for all MS–DRGs. Following this computation, the applicant standardized the charges on each of the identified claims using the FY 2013 factors from the FY 2015 IPPS/LTCH PPS Final Rule Impact File, to match the year of the claims data used

in this analysis (FY 2013 MedPAR file). According to the applicant, charges were not removed for any other specific technologies that may have been used because the applicant expected that a plain balloon will be utilized to predilate the vessel in a majority of drug-coated balloon angioplasty cases prior to the use of the drug-coated balloon (that is, the applicant did not believe it was necessary to remove charges associated with the other specific prior technology (a plain PTA balloon catheter in this case).) The applicant then inflated the average case-weighted standardized charges per case from FY 2013 to FY 2015 using the 2-year inflation factor of 10.44 percent specified in the FY 2015 IPPS/LTCH PPS final rule and added charges related to the new technology to the average charges per case. The final inflated average case-weighted standardized charge per case both for the primary MS–DRGs group and the total MS–DRG group were $82,944 and $101,611, respectively. Because the final inflated average case-weighted standardized charge per case for the applicable MS–DRG exceeds the average case-weighted threshold amounts of $69,594 and $75,215, respectively, using the FY 2015 IPPS Table 10, the applicant stated that the IN.PACT™ Admiral™ technology meets the cost criterion for new technology add-on payments.

In the proposed rule, we stated that we were concerned that both applicants excluded cases of patients that received stent implantations from their analysis because the applicants believed that the technologies can be used instead of stenting procedures. We invited public comments on whether the LUTONIX® and the IN.PACT™ Admiral™ meet the cost criterion.

In their original cost analysis, both applicants included cases with diagnoses of PTA (identified by ICD–9–CM code 39.50) and cases with diagnoses of PAD (identified by diagnosis codes: 440.2x (Atherosclerosis of arteries of the extremities) or 443.9 (Peripheral vascular disease, unspecified)), but excluded cases with stent implantation. The applicants for the LUTONIX® and the IN.PACT™ Admiral™ submitted public comments that responded separately to our concern regarding the rationale for excluding cases involving stenting procedures for the cost analyses. We summarize these comments separately below.

Comment: One of the applicants (Medtronic, the manufacturer of the IN.PACT™ Admiral™ DCB) stated that in its original cost analysis it included cases with procedures of PTA (identified by ICD–9–CM code 39.50) and cases with diagnoses of PAD (identified by diagnosis codes: 440.2x (Atherosclerosis of arteries of the extremities) or 443.9 (Peripheral vascular disease, unspecified)), but excluded cases with stent implantation because it viewed the patient population for PTA diagnoses as similar to the patient population eligible for DCB. The applicant also believed that the resulting analysis would be the clearest and simplest way to demonstrate that DCB meets the new technology add-on payment cost criterion. The applicant further stated that, upon further consideration, it believed that some patients who receive treatment involving stents could otherwise be indicated for and receive DCB therapy instead. In addition, the applicant believed that there may be a proportion of patients who are treated with provisional stenting procedures in addition to DCB therapy. Therefore, in addition to the patients diagnosed with only PTA included in its initial analysis, the applicant provided additional analyses taking into consideration patients treated with stenting procedures.

In its public comment specifically in response to CMS' concern, to demonstrate that the IN.PACT™ Admiral™ technology meets the cost criterion taking into consideration cases involving stent procedures, the applicant performed additional cost analyses and identified all discharges with a diagnosis of peripheral artery disease reported using ICD–9–CM diagnosis code 440.2x (Atherosclerosis of arteries of the extremities) or discharges reporting ICD–9–CM diagnosis code 443.9 (Peripheral vascular disease, unspecified), with a percutaneous transluminal angioplasty (PTA) or stent procedure code using ICD–9–CM procedure code 39.50 (non-coronary angioplasty) or any one of the following ICD–9–CM codes for peripheral vascular stenting procedures: 39.90 (Insertion of non-drug-eluting peripheral (non-coronary) vessel stent(s)); 00.55 (Insertion of drug-eluting stent(s) of other peripheral vessel(s)); or 00.60 (Insertion of drug-eluting stent(s) of superficial femoral artery).

Based on the results of the subsequent analysis, the applicant stated that its assumptions about real-world use of DCBs, based on approximate estimates from internal market models, concluded that: The IN.PACT™ Admiral™ DCB technology could be used to augment the effective treatment of patients diagnosed only with PTA in approximately 42 percent of the cases identified; the IN.PACT™ Admiral™ DCB technology could be used in addition to stents in approximately 25 percent of the cases identified; and the IN.PACT™ Admiral™ DCB technology could replace the use of stents in approximately 33 percent of the cases identified. Using the distribution of potential cases eligible for treatment using the IN.PACT™ Admiral™ DCB technology obtained from internal market research estimates, 42 percent, 25 percent, and 33 percent respectively across the three sources of potential cases eligible for treatment using the IN.PACT™ Admiral™ DCB technology described above, the applicant ascertained an average case-weighted charge per case for ''real-world'' cases involving the IN.PACT™ Admiral™ DCB technology. The final average case-weighted standardized charges per ''real-world'' cases involving the IN.PACT™ Admiral™ DCB technology were $86,037 for the three primary MS–DRGs, and $103,887 for all MS–DRGs. Both of the average case-weighted standardized charges per case exceeded the respective average case-weighted threshold amounts for these sets of MS–DRGs, which are $68,643 for MS–DRGs 252, 253, and 254, and $74,799 for all MS DRGs, respectively. Therefore, the applicant maintained that the IN.PACT™ Admiral™ technology meets the cost criterion for new technology add-on payments.

To address CMS' concern regarding the exclusion of cases involving stent procedures, the applicant for the LUTONIX® technology conducted an additional costs analysis that accounted for cases involving angioplasty and stent procedures by simply adding the charges for both angioplasty and stent procedures to the charges determined in its original analysis. The applicant determined average case-weighted standardized charges per case for the three primary MS–DRGs (MS–DRGs 252, 253, and 254), the five additional MS–DRGs (MS–DRGs 237, 238, 239, 240 and MS–DRG 853) and the other MS–DRGs were $74,039, $83,650, and $90,170, respectively. The applicant determined that the final average case-weighted standardized charges per case for the three primary MS–DRG groups, the five additional MS–DRG groups and across other MS–DRGs were $90,683, $101,298, and $108,498, respectively. Because the final average case-weighted standardized charges per case for all three scenarios exceed the corresponding average case-weighted threshold amounts for the respective MS–DRGs of $68,712, $73,775, and $74,836, respectively, the applicant maintained that the LUTONIX® meets

the cost criterion for new technology add-on payments based on the results of the subsequent cost analysis.

Response: We appreciate both of the applicants' submission of additional information and responses. After review of the applicants' subsequent analyses and consideration of the public comments we received, we believe that both technologies meet the cost criterion.

With regard to substantial clinical improvement for LUTONIX®, the applicant stated that LUTONIX® represents a substantial clinical improvement because it meets an unmet clinical need by providing access to ''no stent zones'' and because it can achieve greater patency; preserve the flexibility of future interventions; and address stent fractures and re-stenosis.[32] [33]

The applicant shared the findings from its LEVANT 1 and LEVANT 2 trials.

LEVANT 1: In the LEVANT 1 trial, 101 patients were randomized to a LUTONIX® drug-coated balloon treatment group or a control group that received percutaneous transluminal angioplasty (PTA) only. The primary endpoint of mean angiographic Late Lumen Loss at 6 months favored the LUTONIX® drug-coated balloon treatment group (0.46±1.13) compared to the control PTA group (1.09±1.07), with a p-value of 0.016.

LEVANT 2: The LEVANT 2 study is the applicant's pivotal study that was conducted as a prospective, multicenter, single blind, 2:1 (test: control) randomized trial comparing the LUTONIX® drug-coated balloon angioplasty to standard balloon angioplasty used during the treatment of patients with femoropopliteal arteries. The applicant documented that the patient characteristics and lesions in both groups were well-matched; 43 percent of patients were diabetic; 35 percent were current smokers; 37 percent were female; and 8 percent had critical limb ischemia.

The study was conducted to show that drug-coated balloon angioplasty improves clinical outcomes for a patient population as compared to currently available treatments. All endpoints were adjudicated by a blinded Clinical Events Committee (CEC) and duplex ultrasound and angiographic core laboratories.

The applicant specified two primary endpoints that must both be met in order for the study to be successful. The first endpoint was primary patency at 12 months, defined as freedom from target lesion restenosis and target lesion revascularization (TLR). The results were the following: Primary patency for LUTONIX® was 65.2 percent compared to primary patency of 52.6 percent for PTA. Kaplan-Meier analysis was 73.5 percent for LUTONIX® compared to 56.8 percent for PTA ($p<0.001$). The second primary efficacy endpoints were composite safety endpoints at 12 months, which included freedom from index-limb amputation; reintervention and related death. The results were 83.9 percent for LUTONIX® compared to 79.0 percent for PTA.

The secondary efficacy endpoints at 12 months for this trial were freedom from Target lesion revascularization (TLR), and the results were 89.7 percent for the LUTONIX® treatment group compared to 84.8 percent for the PTA control group, with p=0.17. Another end point was freedom from target vessel revascularization (TVR), where the result for the LUTONIX® treatment group was 76.2 percent compared to 66.6 percent in the control group with a p-value of 0.041. Clinical indicators, such as ankle brachial index (ABI), Rutherford scores (categorization of symptomology), quality of life (QOL), walking distance, and walking impairment WIQ, were significantly improved with a p-value of <0.001. The applicant assessed the primary safety endpoint using Kaplan-Meier survival analysis and stated that there was no evidence of statistical difference.

Regarding the LEVANT 1 trial, in the proposed rule, we stated our concern that the results of the LEVANT 1 trial were not statistically significant with regard to the p-value documented. In addition, adverse events were similar for both groups and through 24 months; the percentage of patients with any death, amputation, or target vessel thrombosis was 8 percent in the treatment group compared to 12 percent in the control group.

Regarding the LEVANT 2 study, in the proposed rule we stated our concern that the patient population included in the study may not reflect the Medicare population. We also noted that only 37 percent of the studied patients were female. We stated that it could be beneficial to see additional subgroup analyses to test for statistical interaction between treatment and subgroups to ascertain that there is no imbalance in response to different subpopulations, such as males versus females.

We invited public comments on whether LUTONIX® (and IN.PACT™ Admiral™) meets the substantial clinical improvement criterion.

Comment: The applicant submitted public comments in response to CMS' concerns regarding the statistical significance and adverse events documented in the LEVANT 1 trial. The applicant stated that the LEVANT 1 trial was a first-in-human study designed to provide a preliminary look at the efficacy of the LUTONIX® compared to standard PTA, along with a safety assessment of this novel technology in a human clinical study. The applicant reiterated that the primary endpoint for the LEVANT 1 study was angiographic Late Lumen Loss at 6 months. In conclusion, the applicant stated that the data did show a statistically significant benefit from the use of the LUTONIX® over the control PTA group (p-value = 0.016), and the study also assessed clinical endpoints such as target lesion revasculuarization (TLR) at several time points. The applicant further stated that although the study was not designed to show a statistical difference in TLR rates, there was a trend towards superiority for the LUTONIX® over standard PTA treatments.

Response: We appreciate the applicant's submission of additional information in response to our concerns regarding the LEVANT 1 trial. While we do not believe that the results of this trial alone sufficiently demonstrate a substantial clinical improvement, we note that the applicant also submitted additional clinical data in support of its representation of a substantial clinical improvement.

Comment: In response to CMS' concerns regarding the LEVANT 2 study, the applicant and manufacturer of the LUTONIX® technology submitted public comments in which it stated that the proportion of females in the LEVANT 2 study is consistent with other reported randomized superficial femoral artery (SFA) DCB and SFA stent studies, and noted that the percentage of females in the DCB and stent arms for these studies ranges from 29.1 percent to 41.0 percent, and the PTA arm ranges from 33.1 percent to 42 percent. The applicant stated that the LEVANT 2 study enrolled patients at 55 sites globally, including 42 sites across the U.S. to ensure inclusion of a diverse population of patients diagnosed with PAD. The applicant also presented enrollment data from other PAD trials such as the THUNDER, IN.PACT, and ZilverPTX and indicated that the percentages of females enrolled were 35 percent, 35 percent, and 34.3 percent, respectively. The applicant conceded that the LEVANT 2 study was not designed to study subgroups (including

[32] Scheinert, D., *et al.*: Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol, 2005. 45(2): p. 312–5.

[33] Klein, A.J., *et al.*: Quantitative assessment of the conformational change in the femoropopliteal artery with leg movement. Catheter Cardiovasc Interv, 2009. 74(5): p. 787–98.

females). Therefore, the applicant suggested that data analyses from such subgroups should be viewed with caution.

Response: We appreciate the applicant's submission of additional information in response to our concerns regarding the LEVANT 2 trial. We acknowledge and have taken into consideration that there is a historical underrepresentation of women in PAD trials, and the epidemiology and the differential treatment rates between genders may also explain the lower rates of women enrolled in the trial. We note that, while the LUTONIX® LEVANT 2 study was not designed to study subgroups, Medtronic (the co-applicant) submitted a detailed subgroup analysis for the IN.PACT™ Admiral™ technology, which responded to our concerns and is discussed below.

With regard to substantial clinical improvement for the IN.PACT™ Admiral™, the applicant stated that evidence demonstrates that the technology significantly improves key clinical outcomes compared to previous technologies for patients with intermittent claudication. Examples of such key clinical outcomes included a decrease in recurrence of restenosis (disease process); a decrease in rates of repeat interventions (subsequent therapeutic interventions); a decrease in future hospitalizations; improved patient symptoms (decreased pain), and improvement in quality of life and function. To further demonstrate substantial clinical improvement, the applicant asserted that historical proof-of-concept research has demonstrated the utility of various drug-coated balloon technologies in reducing restenosis and reintervention compared with PTA.[34] [35] With this assertion, the applicant stated that there was no evidence of the promising primary patency and target lesion revascularization rates from large randomized controlled trials. This led the applicant to design the IN.PACT™ SFA Trial. The IN.PACT™ SFA Trial is a prospective, randomized-controlled, global, multicenter, single-blinded study conducted with independent, blinded adjudication of all key endpoints. The primary safety end point was freedom from device-related and procedure-related death through 30 days, and freedom from target limb major amputation and clinically-driven TVR through 12 months. The primary effectiveness endpoint was primary patency, a composite endpoint comprising an anatomic measure (binary restenosis as measured by duplex ultrasound or angiography) and a clinical measure (Clinically Driven Target Lesion Revascularization (CD–TLR)). The IN.PACT™ SFA Trial was designed as a two-phase, global, multicenter trial in which 331 patients with symptoms of claudication or rest pain and with a positive diagnostic finding of de novo stenosis and/or non-stented restenotic lesions in the SFA and/or popliteal artery (PPA) were randomized in a 2:1 fashion to treatment with IN.PACT™ Admiral ™ drug-coated balloon or uncoated balloon angioplasty. The trial was prospectively designed to be conducted in two phases: IN.PACT™ SFA Phase I (conducted in Europe) and IN.PACT™ SFA Phase II (conducted in the United States), jointly referred to as IN.PACT™ SFA Trial. According to the applicant, the patient demographics were well-matched, noting that 34 percent of the patients were women.

The applicant noted that, during the SFA Trial, both the study subjects and trial sponsor were blinded to the treatment assignments through completion of the 12-month primary endpoint evaluations. The applicant also stated that the independent Clinical Events Committee and the Core Laboratories were blinded to the treatment assignment and the duration of the follow-up of study participants. In addition, operators (implanting physicians and catheterization laboratory staff, including research coordinators) were not blinded to the treatment delivered due to macroscopic visual differences between IN.PACT™ Admiral™ drug-coated balloon and control technology.

The applicant reported the following: The primary endpoints were: improved primary patency rates in the IN.PACT™ Admiral™ drug-coated balloon arm compared to the control arm; and primary patency within 12 months is defined as freedom from clinically driven target lesion revascularization and freedom from restenosis as determined by duplex ultrasonography peak systolic velocity ratio ≤2.4 or ≤50 percent stenosis as assessed by angiography. Results showed that the 12-month primary patency rate was 82.2 percent in the IN.PACT™ Admiral™ drug-coated balloon arm versus 52.4 percent in the PTA arm (P <0.001). In addition, the 12-month freedom from binary restenosis (assessed by DUS/angiography) was 83.5 percent in the IN.PACT™ Admiral™ drug-coated balloon group compared to 66.3 percent in the PTA group (P = 0.001). The second endpoint measured was Ankle-Brachial Index (ABI) showing 0.951 in the IN.PACT™ Admiral™ drug-coated balloon arm compared to 0.866 in the control arm, P = 0.002. The ABI is an objective hemodynamic measure used to predict the severity of PAD in the lower extremity. The test is done by comparing the systolic blood pressure at the ankle and the systolic blood pressure in the arm while a person is at rest. In general, higher values are better than lower values; a normal resting ankle-brachial index is from 1.0 to 1.4, an abnormal resting ankle-brachial index is 0.9 or lower and an ABI of 0.91 to 0.99 is considered borderline abnormal.[36] Secondary endpoints were primary sustained clinical improvement, defined as freedom from target limb amputation, target vessel revascularization, and increase in Rutherford class; comparing IN.PACT™ Admiral™ with the control arm was 85.2 percent versus 68.9 percent; P <0.001. The rate of repeat target lesion revascularization (TLR), defined by the applicant as repeat revascularization of the target lesion by percutaneous endovascular treatment or bypass surgery, was 2.4 percent in the IN.PACT™ Admiral™ drug-coated balloon arm compared to 20.6 percent in the control arm. In addition, the target vessel revascularization (TVR) procedures (that is, any revascularization done to any segment of the entire target vessel that may reflect restenosis of a target lesion or disease progression causing a new lesion in the target artery) [37] was 4.3 percent in the IN.PACT™ Admiral™ drug-coated balloon arm compared to 23.4 percent in the control arm with a p-value of <0.001).

Other secondary endpoints were conducted and the patients were followed at 1, 6, and 12 months to assess the following claudication symptoms: EQ–5D; Walking Impairment Questionnaire (WIQ); 6-minute walk test in a subset. Claudication symptoms were 7.3 percent in the IN.PACT™

[34] Werk M, Albrecht T, Meyer DR, Ahmed MN, Behne A, Dietz U, Eschenbach G, Hartmann H, Lange C, Schnorr B, Stiepani H, Zoccai GB, Hänninen EL.: Paclitaxel-coated balloons reduce restenosis after femoropopliteal angioplasty: evidence from the randomized PACIFIER trial. Circ Cardiovasc Interv 2012 5: 831–40.

[35] Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwälder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U.: Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. N Engl J Med 2008; 358: 689–99.

[36] Hirsch AT, Haskal ZJ, Hertzner NR, et al.: ACC/AHA guidelines for the management of subjects with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aorta): executive summary. J Am Coll Cardiol 2006;47:1239–312.

[37] Werk M, Langner S, Reinkensmeier B, Boettcher HF, Tepe G, Dietz U, Hosten N, Hamm B, Speck U, Ricke J.: Inhibition of restenosis in femoropopliteal arteries: paclitaxel-coated versus uncoated balloon: femoral paclitaxel randomized pilot trial. Circulation 2008;118: 1358–65.

Admiral™ drug-coated balloon arm compared to 20.7 percent in the control arm. For WIQ (defined as the ability of PAD patients to walk defined distances and speeds, plus climb stairs, thus evaluating claudication severity levels [38]), the gains in improvement were similar in both groups. The 6-minute walk test, which is a measure of functional exercise capacity, was equivocal in both arms. Quality of life (QOL) was measured using five domains of the EQ–5D (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and was found to be equivocal. EQ–5D™ is a standardized instrument for use as a measure of health outcome.[39]

The applicant also conducted extensive subgroup analyses of the primary safety end point, efficacy endpoint, and TLR rates to assess the response to IN.PACT™ Admiral™ in various subpopulations, including: Rutherford category (2, 3, and 4); diabetes; age (≥75); lesion length (<5 cm, ≥5 cm to <10 cm, ≥10 cm to <18 cm); total occlusion, and gender. According to the applicant, although the trial was not designed to power the subgroup analyses, in 9 of these 11 subgroups, patients in the IN.PACT™ Admiral™ treatment group were shown to have statistically significant better outcomes than patients in the PTA control group in the primary effectiveness and safety endpoints as well as clinically-driven TLR. This includes subgroups: Rutherford categories 2 &3; diabetes; age (≥75); lesion length ≥5 cm to <10 cm; lesion length ≥10 cm to <18 cm; total occlusion; and gender (both male and female). In the two subgroups that did not meet statistical significance (Rutherford category 4 and lesion length <5 cm), data for the primary effectiveness and safety endpoints as well as the clinically driven TLR trended in favor of IN.PACT™ Admiral™.

After reviewing the clinical data described above, in the proposed rule we raised a number of concerns related to the substantial clinical improvement criterion. Similar to the LUTONIX® LEVANT studies, in the proposed rule we stated that we were concerned that the IN.PACT™ SFA trial did not match the gender variable. Also, in the proposed rule we stated that we were concerned about the clinical meaningfulness of some of the endpoints measured by the IN.PACT SFA Trial conducted by Medtronic. For example, there were no changes in functional measures such as walking distances. The applicant indicated that this may be because patients in the control group had additional procedures to the point their symptoms were controlled to the same extent as those of the drug-coated balloon group. We stated that we believe that this assertion could be better supported with data. We also cited the higher ankle-brachial index in the drug-coated balloon catheter group as a related example of concern about the clinical meaningfulness of some of the endpoints measured by the IN.PACT SFA trials. While this is also consistent with an enduring physiologic effect of the drug-coated balloon device, we stated our concern that these ABI measurements appear to have been made by unblinded study personnel. As a result, we stated that the IN.PACT™ Admiral™ technology may not be the optimal treatment for all patients diagnosed with peripheral arterial disease. The drug-coated balloon catheter has been compared only with a standard balloon, and no other alternatives, such as stents, surgery, or intensive exercise therapy. Therefore, it is unknown whether a drug-coated balloon strategy would yield the same, better, or worse outcomes than these alternatives. We also noted that while there appears to be broader anatomical applicability, not all of the studies provided definitively indicate that it is a clinical improvement over PTA.

We invited public comments on whether IN.PACT™ Admiral™ (and LUTONIX®) meets the substantial clinical improvement criterion.

Comment: The applicant submitted public comments in response to CMS' concern regarding matching on the gender variable, in which the applicant stated that historically, the proportion of females enrolled in Peripheral Artery Disease (PAD) trials has been lower than that of males. The applicant provided data of lower percentages of women recruited for similar studies. In addition, the applicant noted that evidence suggests that women diagnosed with PAD may be less likely to undergo lower extremity revascularization than men. The applicant further stated that gender differences in the treatment of patients diagnosed with PAD, similar to that found with the treatment patients diagnosed with congestive heart disease (CHD), have been reported. Overall, multiple factors including differences in epidemiology, clinical presentation, and awareness of PAD may have contributed to differential selection for PAD treatment and, by extension, participation in a clinical trial. However, the applicant agreed that it is important to ensure adequate representation of women in PAD trials and address barriers to treatment/trial enrollment.

The applicant further asserted that with respect to outcomes of women treated with IN.PACT™ Admiral™ DCB verses standard PTA options in the IN.PACT SFA Trial, detailed subgroup analyses were carried out to study treatment effects and interactions by gender and other variables. According to the applicant, results show that the use of DCB significantly improved outcomes compared to standard PTA options in both males and females. The primary effectiveness endpoint of primary patency at 12 months was statistically significant in favor of the IN.PACT™ Admiral™ DCB versus standard PTA options for both females and males. Similar findings were observed for the primary safety composite endpoint. In addition clinically-driven target lesion revascularization (TLR) rates were significantly lower in the IN.PACT™ Admiral™ DCB arm versus the PTA arm for both males and females. These gender specific analyses demonstrated no differences in treatment effects between men and women (that is, there was no gender by treatment interaction). The applicant stated that given the statistically significant results for the primary safety and effectiveness endpoints in both genders, it believed that a more balanced enrollment in the male and female subgroups would be expected to show the same results, with tighter confidence intervals.

Response: We appreciate the applicant's response and, as noted above, we have taken into consideration that there is a historical underrepresentation of women in PAD trials in our determination of whether the technology represents a substantial clinical improvement.

Comment: The applicant submitted public comments in response to CMS' concern regarding the clinical meaningfulness of some of the endpoints measured by the IN.PACT SFA Trial. The applicant stated that the IN.PACT™ Admiral™ SFA Trial was designed to assess the safety and efficacy of the IN.PACT™ Admiral™ DCB in treating femoropopliteal artery disease, with primary patency and safety composite as the primary

[38] Jones WS, Schmit KM, Vemulapalli S, Subherwal S, Patel MR, Hasselblad V, Heidenfelder BL, Chobot MM, Posey R, Wing L, Sanders GD, Dolor RJ.: Treatment Strategies for Patients With Peripheral Artery Disease. Comparative Effectiveness Review No. 118. (Prepared by the Duke Evidence-based Practice Center under Contract No. 290–2007–10066–I.) AHRQ Publication No. 13–EHC090–EF. Rockville, MD: Agency for Healthcare Research and Quality; May 2013. Available at: *http://www.effectivehealthcare.ahrq.gov/reports/final.*

[39] *http://www.euroqol.org/.*

endpoints at 12 months. However, the applicant noted that it also assessed important functional and quality of life outcomes as key secondary end points including the EQ–5D and walking impairment (WIQ). The applicant's results showed that patients in the IN.PACT™ Admiral™ DCB arm had better EQ–5D results at 6 and 12 months relative to the baseline than patients in the PTA arm. At 6 months, there was a significantly greater decline in QoL in the PTA arm indicating early treatment failure. At 12 months, the applicant asserted that improvements continued to trend in favor of the IN.PACT™ Admiral™ DCB arm, approaching statistical significance in four of the five domains of the EQ–5D (all domains except anxiety/depression). The applicant noted that, although some of the functional outcome measures did not show statistically significant differences between treatment groups at 12 months, the PTA patients required 8.6 times more target vessel revascularizations to receive the same level of functional performance as IN.PACT™ Admiral™ DCB patients. The applicant asserted that clinically-driven target vessel revascularization (CD–TLR) is a key indicator for failed functional performance and both CD–TLR and primary sustained clinical improvement at 12 months demonstrated statistical significance ($p<0.001$) favoring the IN.PACT™ Admiral™ DCB group. The applicant concluded that patients treated with IN.PACT™ Admiral™ DCB had significantly better primary patency and a marked reduction in the need for target lesion revascularization and associated costs.

Response: We appreciate the applicant's clarification. We believe that our concerns are satisfied by the additional documentation, which indicates that the assessment of the EQ–5D (EQ 5 domains) and walking impairment surveys are sufficient quality of life outcomes that demonstrated trends that favored IN.PACT™ Admiral™ DCB over standard PTA.

Comment: The applicant submitted public comment regarding CMS' concern on the clinical meaningfulness and measurement of the ankle branchial index (ABI) endpoint, in which the applicant stated that ABI is a simple noninvasive diagnostic test of choice when evaluating patients for PAD.[40] [41] The ABI is a result of a calculation based on an objective measurement of the pressures of the patient's ankles/toes and arms. The nurse/technologist performs the ABI/TBI test according to the institutional policy/procedure, using Doppler flow detectors, and immediately records the pressure readings. Because the ABI is a ratio of the blood pressure at the ankle and the arm, the risk of subjectivity in the ABI value is minimal. The applicant further stated the sensitivity and specificity of ABI in diagnosing PAD has been validated using angiograms, and the test was found to have high sensitivity (95 percent) and specificity (100 percent) in diagnosing PAD.[42]

Response: We appreciate the applicant's expanded explanation and input.

Comment: In the applicant's submitted public comment in response to CMS' concern that the IN.PACT™ Admiral™ technology may not be the optimal treatment for all patients diagnosed with peripheral arterial disease, the applicant asserted that the IN.PACT™ Admiral™ DCB is not intended to be the optimal treatment for all patients with PAD and is not indicated for patients diagnosed with below-the-knee PAD. Rather, the applicant explained that the technology is indicated for treatment of de novo or restenotic lesions up to 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4–7 mm (after pre-dilatation). The applicant further stated that current ACC/AHA Guidelines recommend the use of endovascular therapies for treatment of patients with vocational or lifestyle-limiting disability due to intermittent claudication only after inadequate response to exercise or medication, and when there is a favorable risk-benefit ratio. Patients diagnosed with intermittent claudication (IC) eligible for endovascular therapy based on guidelines may benefit from the IN.PACT™ Admiral™ DCB. The applicant believed that there will also be a portion of patients needing provisional stenting, or even surgery to achieve optimal outcomes that may benefit from the IN.PACT™ Admiral™.

Another commenter referenced an article that states that there remains a significant unmet clinical need in patients diagnosed with PAD, as well as a significant progress in the use of vascular procedures (both diagnostic and therapeutic) and preventive care.[43] The commenter recommended that CMS approve new technology add-on payments for the LUTONIX® IN.PACT™ Admiral™.

Response: We appreciate the applicant's submission of the additional data on the specific unmet need that may be met by use of the LUTONIX® and IN.PACT™ Admiral™ technology. We believe that the information provided satisfies our concerns, and the totality of the data from the submitted studies demonstrates that the technologies meet the substantial clinical improvement criterion.

After consideration of the comments we received, we are approving the LUTONIX® and IN.PACT™ Admiral™ technologies for new technology add-on payments for FY 2016. Cases involving the use of LUTONIX® and IN.PACT™ Admiral™ DCBs that are eligible for new technology add-on payments will be identified by one of the ICD–10–PCS procedure codes identified in the table earlier in this section.

Each of the applicants submitted operating costs for its DCB. The manufacturer of the LUTONIX® stated that a mean of 1.37 drug-coated balloons was used during the LEVANT 2 clinical trial. The acquisition price for the hospital will be $1,900 per drug-coated balloon, or $2,603 per case ($1.37 \times $1,900). The applicant projects that approximately 8,875 cases will involve use of the LUTONIX® for FY 2016. The manufacturer for the IN.PACT™ Admiral™ stated that a mean of 1.4 drug-coated balloons was used during the IN.PACT™ Admiral™ DCB arm. The acquisition price for the hospital will be $1,350 per drug-coated balloon, or $1,890 per case ($1.4 \times $1,350). The applicant projects that approximately 26,000 cases will involve use of the IN.PACT™ Admiral™ for FY 2016.

New technology add-on payments for cases involving these technologies will be based on the weighted average cost of the two DCBs described by the ICD–10–PCS procedure codes listed above (which are not manufacturer specific). Because ICD–10 codes are not manufacturer specific, we cannot set one new technology add-on payment amount for IN.PACT™ Admiral™ and a different new technology add-on payment amount for LUTONIX®; both technologies will be captured by using

[40] Lange SF, Trampisch HJ, Pittrow D, Darius H, Mahn M, Allenberg JR. Profound influence of different methods for determination of the ankle brachial index on the prevalence estimate of peripheral arterial disease. BMC Public Health. 2007;7:147.

[41] Shanmugasundaram M, Ram VK, Luft UC, Szerlip M, Alpert JS. Peripheral arterial disease—what do we need to know?. Clin Cardiol. Jun 29 2011;[Epub ahead of print].

[42] Bernstein EF, Fronek A. Current status of noninvasive tests in the diagnosis of peripheral arterial disease. Surg Clin North Am. 1982;62:473–487.

[43] Goodney, Tarulli, Faerber, et al. Fifteen-Year Trends in Lower Limb Amputation, Revascularization, and Preventive Measures among Medicare Patients. JAMA Surg. 2015; 150(1):84–86.

the same ICD–10–PCS procedure code. As such, we believe that the use of a weighted average of the cost of the standard DCBs based on the projected number of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 34,875 cases (26,000 plus 8,875). 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: 25 percent for the LUTONIX® and 75 percent for the IN.PACT™ Admiral™. We then multiplied the cost per case for the manufacturer specific DCB by the case-weighted percentage (0.25 * $2,603 = $662.41 for LUTONIX® and 0.75 * $1,890 = $1,409.03 for the IN.PACT™ Admiral™). This resulted in a case-weighted average cost of $2,071.45 for DCBs. 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 payment for a case involving the LUTONIX® or IN.PACT™ Admiral™ DCBs is $1,035.72 for FY 2016.

e. VERASENSE™ Knee Balancer System (VKS)

OrthoSensor submitted an application for new technology add-on payments for the VERASENSE™ Knee Balancer System (VKS) for FY 2016. The VKS is a sterile, single patient use device to intraoperatively provide a means to dynamically balance the patient's knee during total knee arthroplasty (TKA) surgery. The applicant stated that quantitative metrics, viewed on a monitor through real time wireless information, enable the surgeon to improve soft tissue stability and kinetics during TKA surgery. The VKS device includes a tibial trial insert composed of an array of responsive sensors that delivers quantified kinetic balance data during TKA surgery. Therefore, the applicant believed that the quantitative data provides a basis for the surgeon to make data-based decisions regarding tissue dissection during TKA surgeries, resulting in a more stable outcome.

According to the applicant, the VKS device combines dual sensor elements, coupled with micro-processing technology, to accurately depict intra-articular kinetics and contact point locations within the knee. The tibial trial insert is placed in the knee capsule. Proper placement of the insert does not require any force or infiltration of the bone or soft tissue in the knee. The applicant stated that the VKS device uses wireless communication protocols that overcome line-of-sight or other interference issues, therefore eliminating the need for line-of-sight or direct antenna-based tracking during the TKA surgery.

The first version of the VKS received FDA approval in 2009 for the OrthoRex Intra-Operative Load Sensor. The device was indicated for use as a tool to adjust the femoral knee implant to reduce instability from flexion gap asymmetry using a single patient use sterile force sensor. The applicant noted that the first version of the VKS was not available on the U.S. market at the time of FDA approval in 2009. The applicant stated that the 510K approval from the FDA allowed permission to continue to test the device and improve upon the specificity of the sensors. The applicant stated that the first version of the VKS did not enter on the U.S. market until late 2011. Further advancements were made to the VKS to more accurately refine the sensor specificity, which provides more accurate balance data unique to the contours of specific knee implant components. The applicant further explained that the tibial trial sensor was redesigned to respond quantitatively and specifically to the variations of the contours of specifically manufactured knee implants. The advanced sensor specificity, developed in conjunction with data gained from clinical trials, provides information regarding force and balance metrics that aid the surgeon's understanding and measurement of knee balance. The applicant noted that without the advancements to the sensor specificity, which were perfected based on knowledge gained from the clinical trials, the sensor would not be as clinically useful as it is currently. According to the applicant, these advancements resulted in additional FDA clearances on June 13, 2013, and October 14, 2013, and the product's description was updated on January 28, 2014.

The applicant maintained that the VKS meets the newness criterion for new technology add-on payments. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24453), we stated that we believe that the beginning of the newness period for the VKS commenced when the product was first made available on the U.S. market in late 2011, and the 3-year anniversary date of the product's availability on the U.S. market occurred in late 2014, which is prior to the beginning of FY 2016. We also stated that the advancements made to the VKS that resulted in the additional FDA approval clearances in 2013 may not be significant enough to distinguish the advanced technology from the first version of the VKS, which received FDA approval in 2009. Therefore, we did not believe that the VKS technology could be considered ''new'' for purposes of new technology add-on payments.

As discussed in the FY 2005 IPPS final rule (69 FR 49003), once data become available to reflect the cost of the technology in the relative weights, a technology can no longer be considered ''new'' and eligible to receive new technology add-on payments. Section 412.87(b)(2) states that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs based on available data that reflects the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under this criterion. The applicant analyzed the relative weights from 2010 to 2014 for the MS–DRGs that may contain cases that would be eligible for treatment using the advanced VKS technology (MS–DRGs 461 through 470). As a result of its analysis, the applicant noted that there was no increase in the calculation of the FY 2014 or FY 2015 relative weights for these MS–DRGs that would represent and include the additional cost of cases involving the advanced VKS technology. To the contrary, in the FY 2016 IPPS/LTCH PPS proposed rule, we stated that we believe that the costs of this technology are included in the charge data and the MS–DRGs have been recalibrated using that data. Therefore, we believe that the technology can no longer be considered ''new'' for the purposes of this provision, regardless of whether or not there was an increase in the MS–DRG relative weights during FYs 2014 and 2015, specifically because of the inclusion of the cost of the technology.

Specifically, as discussed in the proposed rule, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814) as part of the newness criterion, 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 the 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.

In evaluating the VKS new technology add-on payment application under the substantial similarity criteria, in the FY 2016 IPPS/LTCH PPS proposed rule, we stated that we believe that the first version of the VKS and the advance version of the VKS use the same mechanism of action to achieve the desired outcome by using a sterile device that is equipped with sensors used to adjust the femoral knee implant to reduce instability from flexion gap asymmetry. In addition, we believe that cases involving the first version of the VKS would be assigned to the same MS–DRG as the cases involving the advanced VKS. Moreover, it appeared that both the first version of the VKS and the advanced version of the VKS would treat the same or similar disease and the same or similar patient population. We concluded that, because the technology appeared to meet all three elements of the substantial similarity criteria, we believe that the beginning of the newness period for this technology would commence when it became available on the U.S. market in late 2011, and therefore the VKS may not be considered ''new'' for purposes of new technology add-on payments.

We invited public comments regarding whether or not the VKS technology is substantially similar to existing technologies, and whether or not the VKS technology meets the newness criterion.

Comment: The applicant submitted comments in response to our concerns regarding whether the anniversary date of entry onto the U.S. market for the VKS is within the 2 to 3 year limit in accordance with the newness criterion. According to the applicant, the technical evolution of the device received FDA 510k clearance in June 2013 based on a completely new operating principal and expanded functionality (tibia and overall limb alignment), which is representative of the advanced version of the device currently used. The applicant further stated that, in addition to the ability to measure both load and alignment of the knee (which are capabilities of the evolved use of the device since the FDA clearance was granted in June 2013), there also has been effective use of the technology in a revision knee capacity, which is an added indication that is currently under review by FDA for clearance as an additional indication for the use of the technology. The applicant believed that improved TKA outcomes lead to greater mobility, reduced morbidity, and a reduced need for revision knee surgery as evidenced by experience demonstrating that the use of the TKS device leads to a more stable TKA and, subsequently, to a significantly reduced probability of the need for revision TKA procedures. The applicant added that the approval of new technology add-on payments for this technology would enable broader access to the benefits of the TKS's capabilities and allow patients to experience statistically significantly improved TKA outcomes. The applicant also noted that new technology add-on payment newness criterion dictates eligibility by limiting the product's ''newness'' classification within the statutory time of 2 to 3 years, and recognized that the intent of the limit is to ensure that there is no current data reflecting the cost of the new technology that would be used to recalibrate the MS–DRGs. However, the applicant explained that the charges and costs relating to the use of the advanced version of the new technology (which is the subject of the application) are not reflected in the most current claims data and have not been used to recalibrate MS–DRGs and, therefore, the MS–DRG payment rate otherwise applicable to the cost of procedures involving the use of the advanced version of the new technology would be inadequate.

Response: We appreciate the details included in the applicant's response to distinguish the 2013 advanced version of the VKS that received FDA clearance from prior versions of the technology, which also have received FDA approvals. However, after considering the information provided, we continue to believe that the advancements made to the VKS that resulted in the additional FDA approval clearances in 2013 are not significant enough to distinguish the advanced version of the technology from the first version of the VKS, which received FDA approval in 2009. In addition, in examining the FDA labeling included in the FDA approvals in 2009 and 2013, we recognize that the language from the labeling included in the 2013 FDA approval does not reflect the changes mentioned by the applicant with regard to its indications and use. Therefore, it appears that data of the current version of the VKS is already reflected within the MS–DRGs. We discuss the comments related to the substantial similarity components of the newness criterion, including MS–DRG assignment of cases involving this technology, in our responses to other comments below.

Comment: In response to CMS' concerns whether the 2013 advanced version of the VKS device has a different mechanism of action than the previous version of the VKS device, the applicant explained in its comment that the mechanism of action for the 2013 FDA-cleared advanced version of the VKS uses novel proprietary changes to the electrical engineering principles in order to capture, measure, analyze, and report measures of load, balance, alignment and rotational congruency, which, when compared to the 2009 FDA-approved device, uses a different mechanism of action. The applicant noted that this development was a significant engineering change requiring reworking of the programs for the sensors, including modifying the internal design, placement, and programming to correctly capture and report measurements related to balance, load, and alignment relative to rotational congruency across the tibial plateau.[44] The applicant indicated that the advanced version of the VKS device that received FDA clearance in 2013 made note of the expanded capability, which added measurement of ''alignment,'' whereas the capability of the prior VKS device design could only measure load and balance.

The applicant further noted that, when comparing this advanced device to its predecessor, its use produces patient outcomes that are similar because both devices measured load relative to ligament balance, and outcomes were measured as a function of load. The applicant stated that the advanced device approved by the FDA in 2013 has the ability to uniquely report relative femoro-tibial rotation and has changed the variables regarding how the surgeon can use the device relative to the soft tissue (ligament) dissection and implant positioning, which allows the surgeon to better measure varus/valgus angles relative to load and balance, and allows for empirically-based decisions used in making angular cuts for both primary and revision TKA procedures. The applicant believed that the introduction of new engineering principles used in the 2013 FDA-cleared advanced version of the VKS device captures, measures, and reports more accurately intercompartmental load,

[44] Roche MW, Elson LC, Anderson CR. A Novel Technique Using Sensor-Based Technology to Evaluate Tibial Tray Rotation. Orthopedics. 2015 Mar 1;38(3).

overall limb alignment, and component rotation, which significantly distinguishes its capabilities from the prior version of the VKS device.

Response: We appreciate the information and details included in the applicant's comment. However, we remain concerned that the 2013 FDA-cleared advanced version of the VKS uses the same mechanism of action as the prior versions of the VKS that previously received FDA clearance in 2009 and 2011. We note that each technology previously approved for this device used similar mechanisms of action to balance a patient's knee joint during TKA surgery. In addition, it is unclear whether the device's current engineering changes, which include the added capability of measurement for knee joint load, balance, and limb alignment, resulted in improvements that go beyond what could be considered a software patch to make adjustments to refine the computation of kinetic knee joint stability and ''balance.'' Therefore, we do not believe there has been a change in the mechanism of action with the current VKS device.

Comment: In response to CMS' concerns whether cases involving the advanced version of the VKS device would be assigned to the same MS–DRG as cases involving the previous versions of the VKS device, and whether each version of the VKS device could be used to treat the same or similar disease and the same or similar patient population, the applicant in its comment stated that it believed that cases representing patients requiring revision knee surgery, which map to MS–DRG 466, 467 and 468 (Revision of Hip or Knee replacement with MCC, with CC, and without CC/MCC, respectively), would now be eligible for evaluation as candidates eligible for treatment using the advanced version of the VKS device. The applicant believed that a new population of patients exists that could benefit from treatments in which intraoperative use of the VKS device can be further validated and improve upon the outcomes of these types of procedures. The applicant further explained that engineering advances extended the VKS' capabilities that created a seamless surgical process supporting key intraoperative challenges of revision knee surgery. The applicant stated that the ability to gain a seamless surgical flow during complex surgery, and having refined metrics including load and balance relative to the anatomy of a revision, enables surgeons to consider a new patient population. The applicant noted that the prior versions of the VKS device could not accommodate varus/valgus angles, and did not have the refined ability to provide information for angular bony cuts. The applicant stated that the advancements achieve outcomes based on a different mechanism of action that provides a higher degree of accuracy when reporting load, alignment, and balance, which enables accurate localization of load using metrics that convert to surgeon dissection specific to the patient's knee. The applicant believed that these advancements also allow a new population of patients to be considered for these types of procedures that map to MS–DRGs 466, 467, 468.

Response: In examining the FDA labeling included in the FDA approvals and indications for the technology's uses from 2009 and 2013, we do not recognize any language in the labeling included in the 2013 FDA approval of the advanced version of the VKS that reflects the changes in indication or recommend use, as mentioned by the applicant. Therefore, we are unable to determine if the advancements made to the 2013 FDA-cleared version of the VKS are significant enough that cases involving the advanced version would not be assigned to the same or different MS–DRGs or involve the treatment of the same or different patient population as would cases involving the previously FDA-cleared versions of the VKS.

As stated in section II.G.1.a. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule and this final rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. In the proposed rule, we noted that the applicant had applied for a new ICD–10–PCS procedure code at the March 18–19, 2015 ICD–10–CM/PCS Coordination and Maintenance Committee Meeting. In this final rule, we note that the new ICD–10–PCS procedure codes XR2G021 (Monitoring of Right Knee Joint using Intraoperative Knee Replacement Sensor, Open Approach, New Technology Group 1) and XR2H021 (Monitoring of Left Knee Joint using Intraoperative Knee Replacement Sensor, Open Approach, New Technology Group 1), were established as shown in Table 6B (New Procedure Codes), which will uniquely identify procedures involving the VKS technology. More information on this request and the approval can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html* and the FY 2016 New ICD–10–PCS Codes can be found at the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*.

With regard to the cost criterion, the applicant supplied three analyses to demonstrate that it meets the cost criterion. The applicant believed that cases that are eligible for the VKS technology map to MS–DRGs 461 and 462 (Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC and without MCC, respectively), MS–DRGs 466 through 468 (Revision of Hip or Knee replacement with MCC, with CC, and without CC/MCC, respectively), and MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with MCC and without MCC, respectively). The first analysis used data from the 2012 National Inpatient Sample (NIS) from the Agency for Research and Quality (AHRQ). We note that the NIS includes Medicare, Medicaid, and commercial and uninsured claims data. However, the applicant limited its search to Medicare cases only.

The applicant searched for all Medicare cases assigned to MS–DRGs 461 and 462 and found 812 and 14,200 cases respectively (for a total of 15,012 cases). The applicant noted that the 15,012 cases assigned to MS–DRGs 461 and 462 also include cases representing hip revision procedures. Therefore, to determine the number of eligible cases reporting bilateral knee revisions assigned to MS–DRGs 461 and 462, based on clinical information, [45] the applicant approximated that 4 percent of the cases assigned to MS–DRGs 461 and 462 represent Medicare beneficiaries who may be eligible for the VKS for a bilateral knee revision procedure. As a result, the applicant focused its analysis on 32 cases assigned to MS–DRG 461 (812 cases * .04), and 568 cases assigned to MS–DRG 462 (14,200 cases * .04). In the FY 2016 IPPS/LTCH PPS proposed rule, we stated we were concerned that the statistical data obtained from clinical information that the applicant used to determine the percentage of cases representing bilateral knee revisions still includes cases representing hip revision procedures. Specifically, the applicant did not uniquely identify cases representing bilateral knee revisions and only produced a percentage of all cases that still includes cases for hip revision procedures.

According to the applicant, eligible cases for the VKS technology include cases representing knee revision procedures that also map to MS–DRGs 466 through 468 (which represent

[45] Memtsoudis SG, Valle AGD, Besculides MC, Gaber, Sculco TP.: In-hospital complications and mortality of unilateral, bilateral, and revision TKA. 2008, Clin Orthop Relat Res, 466:2617–2627.

degrees of severity calculated for each MS–DRG). To determine the number of eligible cases reporting knee revision procedures assigned to MS–DRGs 466 through 468, the applicant first searched the NIS database for the total number of Medicare cases assigned to these MS–DRGs. This resulted in a total of 54,105 cases. The applicant noted that MS–DRGs 466 through 468 also include cases for hip and knee revision procedures. Therefore, to determine the number of cases representing knee revision procedures in each of these three MS–DRGs, the applicant first divided the number of Medicare cases for each MS–DRG (5,195 for MS–DRG 466, 28,650 for MS–DRG 467, and 20,260 for MS–DRG 468) by the total number of Medicare cases assigned to MS–DRGs 466, 467, and 468 (54,105). The applicant then multiplied the percentage for each MS–DRG (9.6 percent for MS–DRG 466, 52.9 percent for MS–DRG 467, and 37.4 percent for MS–DRG 468) by the total amount of cases assigned to each MS–DRG. Based on this calculation, the applicant approximated the following number of cases representing knee revision procedures assigned to each of these three MS–DRGs: 3,054 cases in MS–DRG 466; 16,842 in MS–DRG 467; and 11,910 in MS–DRG 468. In the proposed rule we stated that the methodology the applicant used to determine the percentage of cases representing knee revision procedures still includes cases representing hip revision procedures. Specifically, in its methodology, the applicant did not use any source of statistical relevance to isolate cases representing knee revision procedures. Rather, the applicant used the percentage of Medicare cases assigned to each MS–DRG of the overall total cases for the three MS–DRGs, which includes knee and hip revisions, and multiplied by this percentage to further reduce the total number of cases. We stated that we do not believe that this further reduction to the total number of Medicare cases has sufficiently isolated cases representing knee revision procedures.

According to the applicant, eligible cases for the VKS technology also include TKA procedures that map to MS–DRGs 469 and 470. To determine the number of eligible cases reporting TKA procedures assigned to MS–DRGs 469 and 470, the applicant first searched the NIS database for the total number of Medicare cases assigned to these MS–DRGs. This resulted in 35,740 cases in MS–DRG 469 and 547,955 cases in MS–DRG 470. The applicant noted that MS–DRGs 469 and 470 also include cases representing hip replacement and other joint replacement procedures. Therefore, in order to determine the number of TKA procedures within these MS–DRGs, the applicant searched the NIS database for cases reporting ICD–9–CM procedure codes that typically map to these MS–DRGs. The applicant first searched for cases representing TKA across all MS–DRGs that reported ICD–9–CM procedure code 81.54 (Total knee replacement) and found 336,050 cases. The applicant then searched the NIS database for cases representing hip and other joint replacement procedures across all MS–DRGs that reported ICD–9–CM procedure codes 81.51 (Total hip replacement), 81.52 (Partial hip replacement), 81.56 (Total ankle replacement), 81.57 (Replacement of joint of foot and toe), and 81.59 (Revision of joint replacement of lower extremity, not elsewhere classified) and found 238,050 cases. This resulted in a total of 574,100 cases representing knee, hip, and other joint replacement procedures.

The applicant then divided the number of cases representing TKA procedures by the total number of cases (336,050/574,100) and determined that 58.5 percent of all cases assigned to MS–DRGs 469 and 470 are related to TKA procedures. The applicant then multiplied the percent of cases representing TKA procedures (58.5 percent) by the number of cases assigned to MS–DRGs 469 and 470, which resulted in 20,920 cases in MS–DRG 469 (35,740 * .585) and 320,746 cases in MS–DRG 470 (547,955 * .585). In the proposed rule we stated we were concerned that the methodology the applicant used to determine the percentage of cases representing TKA procedures still includes cases representing hip and other joint replacement procedures. Specifically, the applicant did not uniquely identify cases representing TKA procedures and only produced a percentage of all cases, which still includes cases representing hip and other joint replacement procedures.

Based on the analysis above, the applicant asserted that the total number of cases across MS–DRGs 461 and 462 and MS–DRGs 466 through 470 was 374,071. The applicant determined an average case-weighted charge per case of $57,341. The applicant then determined that it was necessary to remove charges related to the other computer-assisted devices/technologies used during these procedures and charges for operating room time because procedures involving the VKS do not require operating room time, and the charges for the VKS technology would inevitably be different. Therefore, the applicant removed approximately $146 from the average case-weighted charge per case for cases assigned to MS–DRGs 461 and 462, and $73 from the average case-weighted charge per case for cases assigned to MS–DRGs 466 through 470. The applicant noted that the $146 in charges removed from the average case-weighted charges per case for cases assigned to MS–DRGs 461 and 462 was slightly higher than the charges removed from cases assigned to MS–DRGs 466 through 470 because these charges were for bilateral procedures which require additional operating room time.

Data from the NIS database is only available on a national level and not on a hospital-specific level. Therefore, in order to standardize the charges per case, the applicant used the FY 2012 IPPS Impact File and the mean value of all relevant standardization factors to standardize the charges per case. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24455), we stated that the analysis provided by the applicant did not use hospital-specific data and, therefore, the standardization process may be inaccurate because of the use of mean factors rather than hospital-specific factors. By using mean factors rather than hospital-specific factors, we stated that we believe that the standardization performed by the applicant does not sufficiently take into account hospital variations.

The applicant then inflated the charges using an inflation factor of 10.4227 percent based on the inflation factor in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379), and added the charges related to the VKS technology to the adjusted average case-weighted standardized charge per case. This resulted in a final inflated average case-weighted standardized charge per case of $68,121. Using the FY 2015 IPPS Table 10 thresholds, the applicant determined that average case-weighted threshold amount for MS–DRGs 461 and 462 and MS–DRGs 466 through 470 is $57,341. Because the final inflated average case-weighted standardized charge per case for the applicable MS–DRGs exceeds the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

The applicant's second analysis used data from the 2013 American Hospital Discharge Data (AHD) based on 57 randomly selected hospitals. The applicant searched the data and did not find any cases assigned to MS–DRG 461. The applicant noted that it used a value of 10 cases for its analysis of cases assigned to MS–DRG 461 because data

reflecting a zero value indicates that the hospital performed less than 10 procedures. The applicant found 533 cases assigned to MS–DRG 462. To determine the number of cases representing bilateral knee revision procedures in MS–DRG 462, similar to the first analysis, the applicant multiplied the total number of cases assigned to MS–DRG 462 by 4 percent, which resulted in 21 cases. Similar to our statement about the first analysis, in the proposed rule we were concerned that the applicant did not uniquely identify cases representing bilateral knee revision procedures and only produced a percentage of all cases, which still includes cases representing hip revision procedures.

To determine the number of eligible cases reporting knee revision procedures assigned to MS–DRGs 466 through 468, the applicant first searched the AHD database for the total number of cases assigned to these MS–DRGs. This resulted in a total of 2,969 cases. Because these MS–DRGs include cases representing hip and knee revision procedures, to determine the number of cases representing knee revision procedures in each of these three MS–DRGs, the applicant first divided the number of cases for each MS–DRG (122 for MS–DRG 466; 1,746 for MS–DRG 467; and 1,101 for MS–DRG 468) by the total number of cases in MS–DRGs 466 through 468 (2,969). The applicant then multiplied the percentage for each MS–DRG (4.1 percent for MS–DRG 466; 58.8 percent for MS–DRG 467; and 37.1 percent for MS–DRG 468) by the total number of cases in each MS–DRG. Based on this calculation, the applicant approximated the following number of cases representing knee revision procedures in each of these three MS–DRGs: 1,307 cases in MS–DRG 466; 18,704 in MS–DRG 467; and 11,794 in MS–DRG 468. Similar to our concerns about the first analysis, in the proposed rule (80 FR 24455), we stated we were concerned that the methodology the applicant used to determine the percentage of cases of knee revision procedures still includes cases representing hip revision procedures. Specifically, in its methodology, the applicant did not use any source of statistical relevance to isolate cases representing knee revision procedures. The applicant simply used the percentage of Medicare cases for each MS–DRG of the overall total cases for the three MS–DRGs, which include knee and hip revision procedures, and multiplied by this percentage to further reduce the number of cases. We stated that we do not believe that this further reduction to the total number of Medicare cases has isolated cases representing knee revision procedures.

The applicant used the same methodology from the first analysis to determine the number of eligible cases representing TKA procedures assigned to MS–DRGs 469 and 470. The applicant searched the AHD database and found 1,217 cases assigned to MS–DRG 469 and 24,620 cases assigned to MS–DRG 470. To determine the number of cases representing TKA procedures within these MS–DRGs, the applicant multiplied the total number of cases within these MS–DRGs by the percentage of 58.5 percent from the NIS database, which represents the percentage of knee replacement procedure cases among the total number of cases representing knee, hip and joint replacement procedures. This resulted in 712 cases in MS–DRG 469 (1,217 * .585) and 14,411 cases in MS–DRG 470 (24,620 * .585). Similar to our concerns expressed earlier (and in the proposed rule), the methodology that the applicant used to determine the percentage of cases representing TKA procedures still includes cases representing hip replacement and other joint replacement procedures. Specifically, the applicant did not uniquely identify cases representing TKA procedures and only produced a percentage of all cases, which still includes cases representing hip and other joint replacement procedures.

Based on this analysis, the applicant asserted that the total number of cases across MS–DRGs 461 and 462 and MS–DRGs 466 and 470 was 46,960. The applicant determined an average case-weighted charge per case of $80,702. For the rest of the analysis, the applicant followed the same methodology as the first analysis. The applicant removed $146 from the average case-weighed charge per case for cases assigned to MS–DRGs 461 and 462 and $73 from the average case-weighted charge per case for cases assigned to MS–DRGs 466 through 470 for charges related to other computer-assisted devices/technologies used during these procedures and additional charges for the use of the operating room.

Similar to the first analysis, the applicant used the FY 2012 IPPS impact file and the mean value of all relevant standardization factors from all hospitals to standardize the charges per case. Similar to our concerns expressed earlier (and in the proposed rule), the analysis provided by the applicant did not use hospital-specific data and, therefore, the standardization process may be inaccurate because of the use of mean factors rather than hospital-specific factors. By using mean factors rather than hospital-specific factors, the standardization performed by the applicant does not sufficiently take into account hospital variations.

The applicant then inflated the charges using an inflation factor of 10.4227 percent based on the inflation factor in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379), and added the charges related to the VKS technology to the adjusted average case-weighted standardized charge per case. This resulted in a final inflated average case-weighted standardized charge per case of $90,515. Using the FY 2015 IPPS Table 10 thresholds, the applicant determined that the average case-weighted threshold amount for MS–DRGs 461 and 462 and MS–DRGs 466 through 470 is $80,699. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount for the applicable MS–DRGs, the applicant asserted that the VKS technology meets the cost criterion.

The applicant's third analysis used data from the FY 2015 CMS Before Outliers Removed (BOR) file. The BOR file contained 469 cases in MS–DRG 461 and 9,396 cases in MS–DRG 462. To determine the number of cases representing bilateral knee revision procedures assigned to MS–DRGs 461 and 462, similar to the first analysis, the applicant used an assumption of 4 percent, which resulted in 19 cases in MS–DRG 461 and 376 cases in MS–DRG 462. Similar to our concerns stated earlier (and in the proposed rule (80 FR 24456)), the applicant did not uniquely identify cases representing bilateral knee revision procedures and only produced a percentage of all cases, which still includes cases representing hip revision procedures.

To determine the number of eligible cases reporting knee revision procedures assigned to MS–DRGs 466 through 468, the applicant again analyzed the BOR file which contained a total of 44,420 cases. Similar to first two analyses, because these MS–DRGs include cases representing hip and knee revision procedures, to determine the number of cases representing knee revision procedures in each of these three MS–DRGs, the applicant first divided the number of cases for each MS–DRG (4,202 for MS–DRG 466; 23,390 for MS–DRG 467; and 16,828 for MS–DRG 468) by the total number of cases in MS–DRGs 466 through 468 (44,420). The applicant then multiplied the percentage for each MS–DRG (9.5 percent for MS–DRG 466; 52.7 percent for MS–DRG 467; and 37.9 percent for MS–DRG 468) by the total number of

cases in each MS–DRG. Based on this calculation, the applicant approximated the following number of cases representing knee revision procedures in each of these three MS–DRGs: 3,009 cases in MS–DRG 466; 16,747 in MS–DRG 467; and 12,049 in MS–DRG 468. Similar to our concerns stated earlier (and in the proposed rule), the methodology the applicant used to determine the percentage of cases representing knee revision procedures still includes cases representing hip revision procedures. Specifically, in its methodology, the applicant did not use any source of statistical relevance to isolate cases representing knee revision procedures. Rather, the applicant used the percentage of Medicare cases for each MS–DRG of the overall total number of cases for the three MS–DRGs, which includes cases representing knee and hip revision procedures, and multiplied by this percentage to further reduce the number of cases. We stated that we do not believe that this further reduction to the total number of Medicare cases has isolated cases representing knee revision procedures.

The applicant used the same methodology from the first analysis to determine the number of eligible cases reporting TKA procedures assigned to MS–DRGs 469 and 470. The BOR file contained 27,737 cases in MS–DRG 469 and 437,649 cases in MS–DRG 470. To determine the number of cases representing TKA procedures within these MS–DRGs, the applicant multiplied the total number of cases within these MS–DRGs by the percentage of 58.5 percent obtained from the NIS database, which represents the percentage of knee replacement cases among the total number of cases representing knee, hip, and joint replacement procedures. This resulted in 16,236 cases in MS–DRG 469 (27,737 * .585) and 256,178 cases in MS–DRG 470 (437,649 * .585). Similar to our concerns stated earlier (and in the proposed rule), the methodology that the applicant used to determine the percentage of cases representing TKA procedures still includes cases representing hip and other joint replacement procedures. Specifically, the applicant did not uniquely identify cases representing TKA procedures and only produced a percentage of all cases, which still includes cases representing hip and other joint revision procedures.

Based on this analysis, the applicant asserted that the total number of cases across MS–DRGs 461 and 462 and MS–DRGs 466 through 470 was 304,614. The applicant determined an average case-weighted charge per case of $56,282. For the rest of the analysis, the applicant followed the same methodology as the first analysis. The applicant then removed $146 from the average case-weighted charge per case for cases assigned to MS–DRGs 461 and 462 and $73 from the average case-weighted charge per case for cases assigned to MS–DRGs 466–470 for charges related to other computer-assisted devices/technologies used during these procedures and additional charges for the use of the operating room.

Similar to the first analysis, the applicant used the FY 2012 IPPS Impact File and the mean value of all relevant standardization factors from all hospitals to standardize the charges per case. Similar to our concerns stated earlier (and in the proposed rule), the analysis provided by the applicant did not use hospital-specific data and, therefore, the standardization process may be inaccurate because of the use of mean factors rather than hospital-specific factors. By using mean factors rather than hospital-specific factors, we stated that we believe that the standardization performed by the applicant did not sufficiently take into account hospital variations.

The applicant then inflated the charges using an inflation factor of 10.4227 percent based on the inflation factor in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379), and added the charges related to the VKS technology to the adjusted average case-weighted standardized charge per case. This resulted in a final inflated average case-weighted standardized charge per case of $66,382. Using the FY 2015 IPPS Table 10 thresholds, the applicant determined that the average case-weighted threshold amount for MS–DRGs 461 and 462 and MS–DRGs 466 through 470 is $64,280. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount for the applicable MS–DRGs, the applicant asserted that the VKS technology meets the cost criterion.

Based on the information provided by the applicant, combined with the weight of our concerns, in the proposed rule we stated that we were unable to determine if and how the VKS technology meets the cost criterion. We invited public comments on whether or not the VKS technology meets the cost criterion, specifically with regard to the concerns raised.

Comment: The applicant submitted comments in response to CMS' concerns that included an alternative analysis that the applicant conducted to demonstrate that the VKS technology meets the cost criterion. In its analysis, the applicant used the FY 2013 MedPAR file (which contained inpatient hospital claims data for discharges from October 1, 2012 to September 30, 2013) to search for cases involving TKA procedures that reported the following ICD–9–CM procedure codes: 00.80 (Revision of knee replacement, total (all components)); 00.81 (Revision of knee replacement, tibial component); 00.82 (Revision of knee replacement, femoral component); 00.83 (Revision of knee replacement, patellar component); 00.84 (Revision of total knee replacement, tibial insert (liner)); 81.54 (Total knee replacement); and 81.55 (Revision of knee replacement, not otherwise specified). The applicant focused its analysis on MS–DRGs 461 through 470 because these are the MS–DRGs that cases involving TKA procedures typically map to. The applicant noted that that analysis revealed that MS–DRGs 461 and 466 did not contain any cases because the MedPAR claims data do not include hospitals with less than 10 discharges. The applicant identified 283,123 claims (5,417 claims in MS–DRG 462; 2,918 claims in MS–DRG 467; 1,549 claims in MS–DRG 468; 1,673 claims in MS–DRG 469; 271,566 claims in MS–DRG 470). The applicant then standardized the charges, applied an inflation factor of 1.10443 based on the 2-year charge inflation factor listed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379), which resulted in an inflated average case-weighted standardized charge per case of $53,887. The applicant estimated device charges using the cost of the device and the national average CCR of 0.28, and additional charges for operating room time related to the device. The applicant combined these charges with the inflated average case-weighted standardized charges per case and determined a final inflated average case-weighted standardized charge per case of $65,571. The average case-weighted threshold amount in the FY 2015 IPPS Table 10 for these MS–DRGs was $61,870. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount of $61,870, the applicant maintained that the VKS meets the cost criterion using this analysis.

Response: We appreciate the applicant providing this alternative analysis under the cost criterion. After consideration of the additional information provided, we have determined that the VKS technology meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the VKS technology represents a substantial clinical

improvement. The applicant stated that the device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The applicant explained that the use of the VKS technology has improved patient outcomes, including rapid recovery of patients diagnosed with comorbidities, the early return to normal activities, and increased levels of activity and functionality. The applicant noted that patients treated using the VKS technology during TKA procedures did not experience readmission within 30 days, nor was it necessary for the treating physician (the surgeon) to complete a problem focused medical evaluation during the patient's recovery. The applicant further noted that patients having a more favorable immediate outcome with a stable TKA were shown to return to normal function more rapidly than patients with unbalanced knees. Therefore, the applicant stated that patients with complex medical conditions would be able to respond to the early return of normal daily living.

The applicant also believed that the device offers the ability to diagnose a medical condition for a patient population experiencing medical conditions that are currently undetectable, or offers the ability to diagnose a medical condition earlier than that which is capable using currently available technologies. The applicant explained that the VKS technology provides an improved evaluation/diagnosis compared to an unbalanced TKA implant. Specifically, the applicant stated that the device enables the surgeon to obtain intraoperative measures enabling the surgeon to improve upon the placement of the TKA tibial and femoral components. In addition, the applicant stated that, intraoperatively, the device leads to an immediate diagnosis of an implant that can now be accurately positioned due to informed fine tissue dissection. The applicant further stated that the intraoperative technique has been demonstrated to result in increased implant stability and functional congruence. The applicant cited the following examples of outcomes that have been frequently documented and evaluated within clinical studies of medical devices:

- Intended to address the leading causes of early implant failure in TKA: instability, malrotation and malalignment;[46]
- Dynamic intercompartmental load data and Kinetic Tracking enables evidence based soft tissue releases to improve stability through full ROM;[47]
- Provides intraoperative feedback on tibial-femoral component rotation, position of femoral Contact Points and femoral roll-back to facilitate optimal component position;
- Enables reproducible, teachable surgical technique through quantifying surgeon ''feel''; and
- Captures intraoperative data for inclusion in patient EMR, registries or comparative effectiveness studies.

The applicant stated that use of the device significantly improves clinical outcomes for a patient population experiencing these types of medical procedures when compared to currently available treatments. The applicant explained that extensive research and development has resulted in the VKS technology demonstrating improved patient outcomes in multi-center studies. The applicant further explained that the VKS technology has intraoperatively provided a unique opportunity to observe the short-term clinical outcomes of patients with a quantifiably balanced knee versus those who have quantifiably unbalanced knees. According to the applicant, in a multi-center study, the use of the VKS technology has been shown to reduce post-operative pain and improve activity and patient satisfaction scores with statistical significance. Additionally, the applicant stated that 97 percent of patients whose knees were balanced using the VKS technology reported that they were ''satisfied'' to ''very satisfied'' at 1-year post-operative compared to 81 percent patient satisfaction after a TKA procedure without the use of the VKS technology. The applicant stated that the VKS technology provided a 16-percent improvement in patient satisfaction for VKS-balanced knees; the first significantly notable increase of patient-reported satisfaction in over 30 years.[48]

According to the applicant, the use of the VKS technology avoided early implant failure. The applicant explained that considering the objective to ameliorate the present risks of revision in TKA procedures, the VKS technology has been advanced to address the need for improved knee balance through fine tissue dissection using information from the VKS technology intelligent tibial trial. While not disturbing the surgical flow of TKA procedures, the applicant stated that the VKS technology provides the surgeon with data on the dynamic intercompartmental load, and kinetic tracking enables evidence-based soft tissue releases to improve stability through full ROM.[49] The applicant noted that the results of multi-center studies, using the VKS technology intraoperatively, have provided an opportunity to observe the short-term clinical outcomes of patients with a VKS-quantified balanced knee versus those who have VKS-quantified unbalanced knees.

The applicant further stated that the VKS technology provides intraoperative information on tibial–femoral component rotation, position of femoral contact points and femoral roll-back to facilitate optimal component position. One clinical study[50] reported 170 primary TKA procedures where the VKS technology corrected what would have resulted in unbalanced and malrotated implants in 53 percent of the patients. The applicant noted that when referencing the tibial tubercle to maximize tibiofemoral congruency, 53 percent of patients exhibited asymmetrical tibiofemoral congruency in extension. The applicant further stated that of those patients, 68 percent were shown to have excessive internal rotation of the tibial tray relative to the femur, while 32 percent exhibited excessive external rotation. Additionally, the average tibiofemoral incongruency deviated from a neutral position by 6°, ranging from 0.5° to 19.2. The applicant stated that when comparing the VKS with the convention of using the tibial tubercle to maximize tibiofemoral congruency to confirm the final rotation of the tibial tray, the VKS technology provided superior information. The applicant added that data from using the tibial tubercle to maximize tibiofemoral congruency to confirm the final rotation of the tibial tray are highly variable and inconsistent for confirming the final rotation of the tibial tray.

The applicant stated that the VKS technology has demonstrated and resulted in a ''balanced knee'' after TKA procedures with 6 month and 1 year outcome scores showing a significant improvement over conventional or computer-assisted TKA procedures. According to the applicant, by not

[46] Rodriguez-Merchan EC.: Instability Following Total Knee Arthroplasty. *HSSJ* 2011; 7:273–278.

[47] Roche MW, Elson LC, Anderson CR.: A Novel Technique Using Sensor-Based Technology to Evaluate Tibial Tray Rotation. Orthopedics. 2014 (In Press).

[48] Gustke KA, *et al.*: Increased satisfaction after total knee replacement using sensor-guided technology. *Bone Joint J* 2014;96–B:1333–8.

[49] Gustke, Golladay, *et al.*: *A New Method for Defining Balance: Promising Short-Term Clinical Outcomes of Sensor-Guided TKA. The Journal of Arthroplasty* 25 November 2013 (Article in Press DOI: 10.1016/j.arth.2013.10.020).

[50] Roche MW, Elson LC, Anderson CR: A Novel Technique Using Sensor-Based Technology to Evaluate Tibial Tray Rotation. Orthopedics. 2015 (In Press).

disrupting the surgical flow the VKS technology has been viewed by surgeons to provide information enabling them to improve upon the balance of the knee, reduce the degree of rotation and only dissect the fine tissue as needed sparing the release of the ligaments. The applicant further stated that the VKS technology has been shown to enable reproducible, teachable surgical technique through quantifying surgeon ''feel.''

The applicant provided patient outcomes at 6 months and believed that this demonstrated a significant improvement for the ''balanced knee'' TKA procedures using the VKS technology. According to the applicant, multivariate binary logistic regression analyses were performed for both Knee Society Scores (KSS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores at 6 months. Variables run in these analyses included: Age at surgery, body mass index (BMI), gender, preoperative ROM, preoperative alignment, change in activity level (preoperative to 6 months), and joint state (balanced versus unbalanced). For KSS and WOMAC, both step-wise and backward multivariate logistic regression analyses were calculated to be best fit models with similar significance (P=0.001). Ultimately, the step-wise model was used. The applicant stated that the binary model revealed that the variable exhibiting the most significant effect of improvement on KSS and WOMAC scores was balanced joint state (P=0.001; P=0.004). The applicant noted that joint state was the most highly significant variable; this demonstrated similar levels of significance throughout all possible combinations of variables included in the model (P=0.001). The applicant added that joint state was also observed to be the sole significant factor in patient-reported outcome score improvement (P b 0.001).

The applicant added that analysis of the data revealed there was also a concurrent significance observed with activity level (P=0.005). However, the applicant noted that activity level was not significant on its own. The applicant concluded that a balanced joint state results in a higher activity level,[51] which would make activity level more of a dependent variable, rather than a predictor. Therefore, to demonstrate activity level, the applicant used a regression analysis and evaluated KSS and WOMAC scores at 6 months, with odds ratios. According to the applicant, odds ratios were calculated based on meaningful clinical improvement in KSS scores, WOMAC scores, and activity levels at 6 months. In addition, the applicant pointed out that, based on literature review, ''meaningful improvement'' for KSS scores were anything greater than 50 points; WOMAC scores greater than 30 points; and gains in activity level greater than or equal two 2 lifestyle levels (from lowest score to highest: Sedentary, semisedentary, light labor, moderate labor, heavy labor). Also, scores from the unbalanced group were used as the reference point. The applicant stated that odds ratio for balanced joint state and improved KSS score was 2.5, with a positive coefficient (95 percent CI). The applicant believed that this suggested a high probability of obtaining a meaningful improvement in KSS with a balanced knee joint, over those who do not have a balanced knee. According to the applicant, the odds ratio for balanced joint state and improved WOMAC score was 1.3, with a positive coefficient (95 percent CI). The applicant believed that this suggested a favorable probability that patients with a balanced joint state will achieve a meaningful improvement in WOMAC score, over those that do not have a balanced knee. According to the applicant, the odds ratio for balanced joint state and improved activity level was 1.8, with a positive coefficient (95 percent CI). The applicant believed that this also suggested a favorable probability of meaningful gains in activity level in those with a balanced knee, versus those with an unbalanced knee.

The applicant further stated that 1 year clinical trial evidence supports the VKS technology protocol for TKA procedures. According to the applicant, of the 135 patients undergoing sensor-guided surgery, 13 percent remained unbalanced (by surgeon discretion). The applicant stated that ''surgeon discretion,'' in this analysis, indicates that the surgeon recognized and accepted the ''unbalanced'' intercompartmental load difference as presented by the VKS technology, but believed that the knee was in a clinically acceptable state. Pre-operatively, there was no statistical difference in any outcomes measures between the two cohorts, the averages of which were: Total KSS = 105 ±24.6; total WOMAC = 47 ±14.8.

Additionally, according to the applicant, at 1 year, the average total KSS score of balanced patients exceeded that of unbalanced patients by 23.3 points (P<0.001); 179±17.2 and 156±23.4 for the balanced and unbalanced cohort, respectively. The balanced cohort average score for KSS pain and function, separately, were 96.4 and 82.4 respectively; the unbalanced cohort scored 87.8 and 68.3 points for pain and function. The applicant stated that the disparities between the balanced and unbalanced patients' pain and function scores were also highly statistically significant (P<0.001, P=0.022).

For WOMAC, the applicant noted that that the balanced cohort improved their score by 8 points; 10±11.8 and 18±17 for balanced and unbalanced patients, respectively (WOMAC is scored with an inverse scale; lower scores indicate more improvement). The applicant further stated that while this difference did not prove to be statistically significant by the standards set forth for this analysis (P=0.085), the authors believed that this is due, in part, to the large standard deviations associated with both cohorts.

According to the applicant, the balanced cohort's average activity level score was 48.6, which corresponds with the light to moderate labor categories (tennis, light jogging, heavy yard work) and the unbalanced patient's average activity level score was 26.7, which corresponds to the upper limits of the semi-sedentary range (light housework, walking for limited distances). The applicant believed that the difference between the average scores was statistically significant (P=0.015). The applicant noted that the most notable aspect of every outcome measure collected is that the unbalanced patient scores at 1 year still failed to achieve the level of improvement of the balanced patient scores at 6 months.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24458 and 24459), we presented a number of concerns regarding the applicant's assertions regarding substantial clinical improvement. First, we stated that during the trials, after using the device, surgeons continued to make manual adjustments to the spacers to set the knee replacement. The applicant asserted that the VKS technology presents better accuracy for the surgeon when making adjustments to the spacers when implanting a knee replacement. However, we stated that the evidence does not delineate the degree of any improved outcomes or patient satisfaction associated with use of the VKS technology versus additional manual adjustments made by the surgeon. We also stated that most of the clinical evidence is based on patient satisfaction surveys. While the survey data appeared to demonstrate that

[51] Gustke, Golladay, *et al.*: A New Method for Defining Balance: Promising Short-Term Clinical Outcomes of Sensor-Guided TKA. The Journal of Arthroplasty 25 November 2013 (Article in Press DOI: 10.1016/j.arth.2013.10.020).

patient satisfaction improved, we stated that we do not believe the data presented are sufficient to determine if the VKS technology represents a substantial clinical improvement over manual adjustment. Furthermore, the use of historical literature controls might be useful during early clinical development, but there are possible biases and limitations of this research design. Specifically, there could be multiple differences in the pre-procedure clinical characteristics of patients with ''unbalanced'' knees and those with ''balanced'' knees that could affect outcomes, such as more severe initial disease, more pre-operative misalignment, more obesity, or more comorbidity. These and other potential confounders were not documented or adjusted for in the analyses of outcomes in the literature provided by the applicant. Additionally, as discussed above, the applicant released a first version of the VKS technology in 2011 and advancements were made to the VKS technology that resulted in additional FDA clearances in 2013. The applicant stated in its application that the first version is considered the first technology of its kind. Therefore, we stated in the proposed rule that we believe the VKS technology may no longer be considered new. The applicant submitted an application for the advanced version of the VKS technology from 2013. However, the applicant did not present clinical data to distinguish the improvements made to the advanced version from the first version. Therefore, in the proposed rule, we stated that we were unable to determine if the advanced version represents a substantial clinical improvement over existing technologies (that is, the first version of the VKS technology).

We invited public comments on whether the VKS technology meets the substantial clinical improvement criterion, specifically with regard to our concerns.

Comment: One commenter stated that recently published data shows improved short-term results for procedures using the VKS. The commenter further stated that sensor technology similar to that utilized with the VKS technology will become an important tool in achieving optimal clinical outcomes in knee replacement surgery, and encouraged CMS to approve new technology add-on payments to offset the added costs of this new technology and encouraged its expanded use to include a broader population of patients.

Another commenter questioned whether a knee defined as balanced by use of the VKS produced a significantly more favorable outcome than a knee defined as unbalanced by use of the VKS. The commenter stated that improved outcomes have not been demonstrated by the VKS that are significantly increased when compared to improved outcomes achieved with additional manual adjustments made by surgeons.

Response: We appreciate the commenters' input. We considered these comments in our determination of whether the VKS represents a substantial clinical improvement over existing technologies.

Comment: The applicant submitted comments in response to CMS' concerns as to whether the technology demonstrated a substantial clinical improvement. The applicant indicated that its objective has always been to improve the outcome of primary TKA procedures relative to instability, stiffness, pain, and patient immobility. The commenter noted that early findings inspired surgeons to propose measures of ligament balance as a function of load and balance. The applicant explained that the concept of ligament balance has always been a subjective surgical process due to the absence of an objective means to measure variables such as load and alignment intraoperatively. The applicant stated that continued research and development identified ideal load, balance and kinematics as well as rotational alignment metrics now available with the 2013 devices.

According to the applicant, the devices FDA-cleared in June 2013 differ from those used in the early stages (2012) of the study. The applicant stated that engineering changes maintain the prior device measurements of balance as a function of load but the new approval added alignment within these measurements and improves upon the surgical flow, all features which are important to achieve a more stable TKA procedure result. The applicant noted that the device's expanded functionality (from June 2013 clearance) of the addition of alignment has spurred use in revision cases and is a new indication for use in the 510k currently under review.

The applicant also stated that outcome studies represent a series of patients enrolled and operated on by surgeons trained on the technique, using an early device and transitioning to the 2013 engineering changes. The applicant noted that participating surgeons adhered to the study design and surgical protocol and did not make additional manipulations of the knee after the surgeon captured the VKS metrics. The applicant further noted that, early on, some surgeons did not change their tissue dissection based upon the data from the VKS (the device was used merely to collect intercompartmental load data in these cases), as the data assessed from these earlier stage surgical cases were seen to have results indicating unbalanced knees. The applicant stated that early recognition of these ''unbalanced'' knees gave rise to the surgeon now modifying their tissue dissection based on the VKS information and provided an ''unbalanced'' set of patients to compare outcomes.

The applicant also stated that highly statistically significant P-values of 0.0001 were reported using the KSS and WOMAC score. The applicant noted that KSS and WOMAC are validated scoring tools specifically designed to capture patient functional outcomes, including pain scores. The applicant also noted patient satisfaction measures were also collected which demonstrated that the VKS KSS and WOMAC scores were statistically higher than traditional scores for primary TKA or navigated TKA.[52]

The applicant stated that BMI of the VKS balanced cohort was compared to historical TKA controls. The applicant noted that historically patients tend to gain weight after TKA which contributes to poorer outcomes.[53] [54] [55] [56] [57] [58] Rather than gaining weight, as reported in the historical meta-analysis, the applicant further noted that average weight *loss* of the VKS cohort (over 65 years of age)

[52] Gustke K, Golladay G, Jerry G, Roche MW, Elson LC, Anderson CR. Increased Patient Satisfaction After Total Knee replacement using sensor-guided technology. Bone Joint J. 2014 Oct;96–B(10):1333–8.

[53] Mackie A, *et al.*, Association Between Body Mass Index Change and Outcome in the First Year After Total Knee Arthroplasty, J Arthroplasty (2014). Available at: *http://dx.doi.org/10.1016/j.arth.2014.09.003*.

[54] Donovan J, Dingwall I, McChesney S. Weight change 1 year following total knee or hip arthroplasty. ANZ J Surg. 2006; 76(4): 222–225.

[55] Zeni JA, Snyder-Mackler L. Most patients gain weight in the 2 years after total knee arthroplasty: comparison to a healthy control group. (NIH Public Access Manuscript) Osteoarthritis Cartilage. 2010; 18(4): 510–514.

[56] Heisel C, Silva M, dela Rosa MA, *et al.* The effects of lower-extremity total joint replace net for arthritis on obesity. Orthopedics. 2005; 28(2): 157–159.

[57] Riddle DL, Singh JA, Harmsen WS, *et al.* Clinically important body weight gain following knee arthroplasty: a five-year comparative cohort study. Arthritis Care Res (Hoboken). 2013; 65(5): 669–677.

[58] Abu-Rajab RB, Findlay H, Young D, *et al.* Weight changes following lower limb arthroplasty: a prospective observational study. Scott Med J. 2009; 54(1): 26–28.

was 10 lbs. at 1 year.[59] The applicant stated that patients treated with the VERASENSE intraoperative technique defining ''balance and load'' relative to intercompartmental congruency and alignment not only had positive KSS and WOMAC scores, but their improved functional status resulted in a loss of weight and BMI classification when compared to historical controls. The applicant further asserted that the VKS features in the 2013 FDA-cleared advanced version of the device resulted in statistically improved KSS and WOMAC scores as well as a 16-point increase in patient satisfaction measured over 2 years. The applicant concluded that the results offer further substantial clinical evidence that the VKS is a novel tool delivering improved intraoperative surgical skills to the orthopedic surgeon to quantitatively improve their operative technique and thereby give patients highly valued primary TKA outcomes.

Response: As stated above, most of the clinical evidence presented by the applicant is based on patient satisfaction surveys. While the survey data appeared to demonstrate that patient satisfaction improved, we still do not believe that the data presented are sufficient to determine if the VKS technology represents a substantial clinical improvement over existing technique. Specifically, the studies conducted were based on a limited study design, given that the applicant was in the process of establishing the definition of a balanced knee, lending to the possibility of confounding and bias. For example, there was no randomization of participants because physicians were given the discretion whether to use the device. We also noted that this study was a retrospective, observational study that was sufficient to assist in determining the evolving definition of a balanced knee, but not designed to determine if a balanced knee leads to substantial clinical improvement. Finally, as mentioned above, we were concerned that there could be multiple differences in the pre-procedure clinical characteristics of patients with ''unbalanced'' knees and those with ''balanced'' knees that could affect outcomes, such as more severe initial disease, more pre-operative misalignment, more obesity, or more comorbidity. These and other potential confounders were not documented or adjusted for in the analyses of outcomes in the literature provided by the applicant. However, we note that the applicant is currently conducting randomized controlled studies measuring surgical technique and patient outcomes. Overall, based on the clinical evidence provided to date, we are not convinced that the VKS device leads to better outcomes over manual adjustments achieved by currently available treatment options. Therefore, after consideration of the public comments we received, we do not believe that the VKS technology represents a substantial clinical improvement over existing technologies, and we are not approving new technology add-on payments for the VKS technology for FY 2016.

Comment: One commenter stated that the VKS technology shows to be an effective, objective, and technically proficient advance in TKA procedures. The commenter believed that by using the new reengineered 2013 FDA-cleared advanced device, orthopedic surgeons can now quantitatively measure load, ''balance,'' and alignment to achieve optimal implant rotation and relative rotation between the tibial and femoral components, and soft tissue balancing. The commenter noted that tracking patient's readmission rate with ''balanced'' knees did not require a 30-day readmission nor did they require a clinical visit with their surgeon. The commenter stated that the VKS appears to be a valuable innovation that surgeons can implement and patients can derive benefit.

The commenter further stated that published findings provide evidence that the device significantly reduces the incidence of TKA failure due to stiffness and instability. The commenter added that the VKS technology should reduce the need for revision knee surgery and the morbidity patients learn to live with when their implant is not stable or incorrectly placed.

The commenter stated that estimates find Medicare spends over $1 billion annually just on facility and physician payment related to revision knee surgeries. The commenter noted that preventing complications and keeping patients out of acute and long term care facilities saves money and avoids added complications that can result in unintended consequences leading to excessive costs to the healthcare system and the patient. The commenter stated that hospitals have tight margins and recommended that CMS grant the VKS a new technology add-on payment for FY 2016.

The commenter also asserted that engineering advances of the 2013 FDA-cleared advanced device uses data gained from prior research and development consistent with the newness criterion and the demonstration of substantial clinical improvement. The commenter believed that payment for MS–DRGs 469 and 470 is inadequate, and with consideration of the 2013 FDA approval, payment for MS–DRGs 466, 467 and 468 payment would also be inadequate.

The commenter believed that the VKS technology meets all three criteria for new technology add-on payments. The commenter also believed that, in the absence of added payment, surgeons would be denied the opportunity to quantitatively correct fine tissue dissection leading to a correctly ''balanced'' primary TKA and patients would be inappropriately served.

With regard to our first concern on substantial clinical improvement, the commenter stated that surgeons responded to the device metrics early on in the trial for collection only of ''balance'' information in order to establish a baseline for objectively defining what intraoperative balance meant (a definition that, prior to availability of the VKS technology, was not possible). The commenter further stated that upon establishment of a differential ''window'' between medial and lateral compartments of 15 pounds the sensor was then used as a tool to direct soft tissue dissection to achieve an intraoperative balance (within 15 pounds) result. The commenter explained that this cohort of patient results comprised the ''balanced'' population within the trial and, when compared with the ''unbalanced'' cohort (which were predominantly patients who received ''manual adjustments''), showed improved outcomes and patient satisfaction associated with the use of VKS technology.

With regard to our second concern on substantial clinical improvement, the commenter stated that KSS and WOMAC scores are the most reported outcome tools for TKA procedures. The commenter asserted that patient satisfaction scores are equally validated outcome metrics. The commenter noted that the clinical outcomes at 6 months, and 2 years were recently published and reported that the VKS used by a trained surgeon delivers clinical outcomes much better than traditional primary TKA patients compared with the KSS and WOMAC scores. The commenter cited studies that showed patients with balanced knees at 6 months had higher functional outcome scores than

[59] Golladay GJ, Jerry GJ, Gustke KA, Roche MW, Elson L, Anderson C. Post-operative weight gain after total knee arthroplasty: Prevalence and its possible attenuation using intraoperative sensors. Reconstructive Review 2014 March Vol 4, No 138–41.

traditional patients at 2 years.[60] [61] The commenter stated that the scope of 2 to 3 years of the newness criterion makes it impossible to achieve more data, while also designing the best device to achieve the outcomes. The commenter believed that the studies were well-designed, had Institutional Review Board (IRB) approval, and were excellent protocol adherence with outcome data captured correctly.

Response: For the reasons previously stated, we do not believe that the VKS represents a substantial clinical improvement over existing technologies, and we are not approving new technology add-on payments for the VKS for FY 2016.

f. WATCHMAN® Left Atrial Appendage (LAA) Closure Technology

Boston Scientific Corporation submitted an application for new technology add-on payments for FY 2016 for the WATCHMAN® Left Atrial Appendage (LAA) Closure Technology (WATCHMAN® System). (We note that, as discussed in detail later in this section, the applicant submitted an application for new technology add-on payments for FY 2015 for the WATCHMAN® System, but withdrew its application after we issued the FY 2015 IPPS/LTCH PPS proposed rule.) According to the applicant, when a patient has been diagnosed with atrial fibrillation (AF), the left atrium does not expand and contract normally. As a result, the left atrium is not capable of completely emptying itself of blood. Blood may pool, particularly in the part of the left atrium called the left atrial appendage. This pooled blood is prone to clotting, causing formation of a thrombus. If a thrombus breaks off, it is called an embolism (or thromboembolism). An embolism can cause a stroke or other peripheral arterial blockage.

The applicant asserted that the WATCHMAN® System device is an implant that acts as a physical barrier, sealing the LAA to prevent thromboemboli from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for Warfarin therapy for patients diagnosed with nonvalvular AF who are eligible for Warfarin therapy but for whom the risks of long-term oral anticoagulation outweigh the benefits.

With regard to newness criterion, the applicant received FDA approval on March 15, 2015. According to the applicant, the WATCHMAN® System is the first LAA closure device approved by the FDA. Therefore, the applicant believes that the technology meets the newness criterion. Effective October 1, 2004 (FY 2005), ICD–9–CM procedure code 37.90 (Insertion of left atrial appendage device) was created to identify and describe procedures using the WATCHMAN® Left Atrial Appendage (LAA) Closure Technology. As stated in section II.G.1.a. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule and this final rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. Under the ICD–10–PCS, procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) is the comparable translation for ICD–9–CM procedure code 37.90.

In the FY 2016 IPPS/LTCH proposed rule (80 FR 24459), we did not state any concerns regarding whether the WATCHMAN® System meets the newness criterion. We invited public comments on if, and how, the WATCHMAN® System meets the newness criterion.

Comment: One commenter, the applicant, reiterated that the WATCHMAN® System is not substantially similar to any FDA-approved technology currently on the market and satisfies the newness criteria.

Response: We thank the applicant for its additional comments. We agree that the WATCHMAN® System meets the newness criterion. We note that CMS received a formal National Coverage Decision (NCD) request from the manufacturer asking that CMS cover percutaneous, transcatheter, intraluminal LAA closure using an implanted device. We refer readers to the CMS Web site at: *http://www.cms.gov/medicare-coverage-database/details/nca-details.aspx?NCAId=281* for information related to this ongoing NCD. The tracking sheet for this National Coverage Analysis (NCA) indicates an expected NCA completion date of February 19, 2016. The processes for evaluation and determination of an NCD and the processes for evaluation and approval of an application for new technology add-on payments are independent of each other. However, any payment made under the Medicare program for services provided to a beneficiary would be contingent on CMS' coverage of the item, and any restrictions on the coverage would apply.

As discussed in the proposed rule (80 FR 24459), with regard to the cost criterion, the applicant used the FY 2013 MedPAR file (which contained inpatient hospital claims data for discharges from October 1, 2012 to September 30, 2013) to search for cases reporting ICD–9–CM procedure code 37.90. The applicant provided two analyses. The first analysis includes all claims that reported ICD–9–CM procedure code 37.90, regardless of whether the code indicated a principal procedure that determined the MS–DRG assignment of the case. This analysis identified 507 cases across 29 MS–DRGs. The applicant noted that the MedPAR file contained claims that were returned to the provider that reported charges for actual cases from clinical trials that used the WATCHMAN® System that were well below post-FDA approval pricing. Therefore, the applicant removed the premarket device related charges. The applicant then standardized the charges, applied an inflation factor of 1.10443 based on the 2-year charge inflation factor listed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379) and then added post-FDA approval charges for the WATCHMAN® System. Using the anticipated cost of the device after FDA approval and the National Average Implantable Device cost center CCR, the applicant estimated device charges post-FDA approval, combined those with the inflated average case-weighted standardized charges per case, and determined a final inflated average case-weighted standardized charge per case of $150,213. The average case-weighted threshold amount in the FY 2015 IPPS Table 10 for these MS–DRGs was $97,505. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount of $97,505, the applicant maintained that the WATCHMAN® System meets the cost criterion using this analysis.

In the applicant's second analysis, cases eligible for the WATCHMAN® System were identified by claims reporting ICD–9–CM procedure code 37.90 assigned to MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC and without MCC, respectively). The applicant believed that these are the MS–DRGs to which cases are typically assigned if the WATCHMAN® System is used in the principal procedure performed during the inpatient stay. The applicant applied the trims in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49910

[60] Gustke K, Golladay G, Jerry G, Roche MW, Elson LC, Anderson CR. Increased Patient Satisfaction After Total Knee replacement using sensor-guided technology. Bone Joint J. 2014 Oct;96–B(10):1333–8.

[61] Gustke KA, Golladay GJ, Roche M, Elson L, Anderson C. Primary TKA patients with Quantifiably Balanced Soft-Tissue Achieve Significant Clinical Gains Sooner than Unbalanced Patients. Adv Orthop. 2014:628695.

through 49911), which resulted in 369 cases.

As with its first analysis, the applicant determined standardized nondevice charges for the applicable cases using claims data from the FY 2013 MedPAR file and applied an inflation factor. The applicant calculated average nondevice charges by subtracting what the applicant believed was the average total implantable device charges (calculated as the sum of the five individual device charge fields in the MedPAR file that constitute the Implantable Device cost center). Similar to its first analysis, the applicant then standardized the charges, applied an inflation factor of 1.10443, subtracted the device charges reported on the MedPAR claims (reflecting costs during the IDE study) and replaced them with the anticipated charges following FDA approval (converting the costs of the device to charges with a CCR of 0.349 based on the national average implantable device CCR from the FY 2015 IPPS/LTCH PPS final rule (79 FR 49914)), combined those with the inflated average case-weighted standardized charges per case, and determined a final inflated average case-weighted standardized charge per case of $117,663. The average case-weighted threshold amount for these MS–DRGs in the FY 2015 IPPS Table 10 was $72,804. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted MS–DRG threshold amount of $72,804, the applicant maintained that the WATCHMAN® System meets the cost criterion using this analysis. We note that the applicant searched for cases reporting ICD–9–CM procedure code 37.90. In section II.G.3.b. of the preamble of this final rule, we are finalizing a proposal regarding cardiac ablation and other specified cardiovascular procedures. Specifically, we proposed to assign the procedures performed within the heart chambers using intracardiac techniques, including those identified by ICD–9–CM procedure code 37.90, to two new MS–DRGs: MS–DRG 273 (Percutaneous Intracardiac Procedures with MCC) and MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC). In the proposed rule, we stated that we believe that this could have implications for determining whether the applicant meets the cost criterion. There have been instances in the past where the coding associated with a new technology application is included in a finalized policy to change one or more MS–DRGs. For example, in the FY 2013 IPPS/LTCH PPS final rule, we describe the cost analysis for the Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft which was identified by ICD–9–CM procedure code 39.78. In that same rule, we finalized a change to the assignment of that procedure code, reassigning it from MS–DRGs 252, 253, and 254 to MS–DRGs 237 and 238. Because of that change, we determined that, for FY 2013, in order for the Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft to meet the cost criteria, it must demonstrate that the average case-weighted standardized charge per case exceeds the thresholds for MS–DRGs 237 and 238 (77 FR 53360). We note that, in that example, MS–DRGs 237 and 238 existed previously; therefore, thresholds that were 75 percent of one standard deviation beyond the geometric mean standardized charge for these DRGs were available to the public in Table 10 at the time the application was submitted. In the FY 2016 IPPS/LTCH proposed rule, we stated that in this case, if MS–DRGs 273 and 274 were to be finalized for FY 2016, we recognize that thresholds that are 75 percent of one standard deviation beyond the geometric mean standardized charge would not have been available at the time the application was submitted. We stated that we believe that it could be appropriate for the applicant to demonstrate that the average case-weighted standardized charge per case exceeds these thresholds for MS–DRGs 273 and 274. Accordingly, we made available supplemental threshold values on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html* that were calculated using the data used to generate the FY 2015 IPPS/LTCH PPS Table 10 and reassigned the procedure codes in accordance with the finalized policies discussed in section II.G.3.b. of the preamble of this final rule.

In the FY 2016 IPPS/LTCH proposed rule, we invited public comments on whether considering these supplemental threshold values as part of the cost criterion evaluation for this application is appropriate and also on how to address similar future situations in a broader policy context should they occur. We also invited public comments on the whether the WATCHMAN® System meets the cost criterion based on the applicant's analysis.

Comment: Commenters disagreed that it would be appropriate to consider the supplemental thresholds as part of the cost analysis and recommended that CMS continue its current policy to evaluate the cost threshold provided by the applicant at the time an application is submitted. One commenter argued the following three reasons why CMS should maintain the current policy: (1) An application with newly created MS–DRGs will be treated differently than an application associated with a procedure whose MS–DRGs are not newly created and, therefore, will be held to a higher standard, a standard that is beyond an applicant's control; (2) applicants whose applications are associated with a procedure that CMS proposed to be reassigned to a newly created MS–DRG will have less time to review the supplemental thresholds; and (3) a short period of time makes it more difficult to review or verify CMS' calculations of the supplemental thresholds. Another commenter stated that the primary purpose of the final rule is to establish the processes and values that will be used during the next fiscal year. Therefore, the commenter asserted that CMS review should be conducted based on the same MS–DRGs and associated cost thresholds from the final rule and these thresholds should be the basis of CMS' determination whether the applicant satisfies the cost criterion.

Commenters urged CMS to consider using the following sequence for new technology add-on payment applications that are associated with procedures that CMS proposes be reassigned to newly created MS–DRGs: First, CMS should evaluate the cost threshold in effect at the time the new technology add-on payment application is submitted to determine if an applicant exceeds the cost threshold. Second, CMS should determine if the application meets the new technology add-on payment criteria, including the cost threshold, in place at the time the new technology add-on payment was submitted. Third, CMS should reassign procedures associated with new technology add-on payments to a different MS–DRG after the new technology add-on payment decision is made. One commenter stated that such a sequence would be identical to the current policy CMS uses when reassigning procedures already associated with a new technology add-on payment to new DRGs. The commenter further stated that in cases when CMS reassigns procedures already associated with a new technology add-on payment to a different set of DRGs than were originally used to determine if the applicant met the cost criterion, CMS does not require the new technology add-on payment to be reassessed using cost thresholds for the newly assigned MS–DRGs. The commenter noted that CMS did not

reassess in the FY 2016 IPPS/LTCH PPS proposed rule whether the MitraClip® System (which was approved for FY 2015 new technology add-on payments) meets the cost criterion using the supplemental table values for the newly created DRGs 273 and 274 into which CMS proposed reassigning the procedure associated with MitraClip® System. The commenter stated that it believed CMS should follow the same process for the WATCHMAN® System this year and other applications in the future (should the need arise).

Response: We agree with the commenters that we should evaluate the cost threshold in effect at the time the new technology add-on payment application is submitted to determine if an applicant exceeds the cost threshold. We agree that this policy is most predictable for applicants. For the same reason, we are maintaining our current policy to use the thresholds issued with each final rule for the upcoming fiscal year (that is, for FY 2017 we will use Table 10 issued with this FY 2016 final rule, along with any updated MS–DRG assignments) when making a determination to continue add-on payments for those new technologies that were approved for new technology add-on payments from the prior fiscal year.

Comment: The applicant submitted a public comment using the methodology and analysis above to further demonstrate the WATCHMAN® System meet the cost criterion compared to the supplemental thresholds.

Response: We thank the applicant for providing this additional analysis. As discussed above, we are using the thresholds from FY 2015 to determine if the WATCHMAN® System meets the cost criterion. Based on the analysis described in the proposed rule, we have determined that the WATCHMAN® System meets the cost criterion.

Regarding the substantial clinical improvement criterion, we note that the applicant applied for new technology add-on payments for FY 2015 (as discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28043 through 28045)). However, prior to the publication of the FY 2015 IPPS/LTCH PPS final rule, the applicant withdrew the application. Before the withdrawal of the application, CMS stated its concerns with the application in the FY 2015 IPPS/LTCH PPS proposed rule. The applicant included responses to CMS' previous concerns with the FY 2015 application in its FY 2016 application. Therefore, we addressed the applicant's responses to the previous concerns specified in the FY 2015 IPPS/LTCH PPS proposed rule as well as our observations on the current FY 2016 application in the FY 2016 IPPS/LTCH PPS proposed rule, as we set forth below.

The applicant asserted that the WATCHMAN® System, a system that reduces the risk of thromboembolic stroke in patients diagnosed with high-risk nonvalvular AF who are eligible for Warfarin therapy, but in whom the potential risks of Warfarin therapy outweigh the potential benefits, meets the substantial clinical improvement criterion because the WATCHMAN® System is superior to currently available treatments. The applicant claimed that the WATCHMAN® System is ideal for patients diagnosed with a prior hemorrhagic stroke while on Warfarin therapy, patients not adherent to Warfarin therapy, patients with difficulty achieving a therapeutic international normalized ratio (INR), and patients with an increased risk or history of falls. The applicant acknowledged that anticoagulation using Warfarin therapy or one of the novel oral anticoagulation agents (NOACs), such as dabigatran, rivaroxaban, or apixaban, is effective for preventing thromboembolism in patients who can tolerate such medication over the long term. However, these medications are associated with certain risks. The applicant stated that the most used and studied agent, Warfarin, requires dietary restrictions, has a high-risk of drug interactions, genetic variability in dose-response, and the need for frequent monitoring. According to the applicant, the average patient diagnosed with AF and treated with Warfarin therapy achieves a therapeutic INR for approximately one-half of the treatment time. The applicant further stated that these NOACs also have nonadherence risks, high discontinuation rates (up to 20 percent within 2 years), are difficult to monitor effectiveness, and in some cases have no readily available reversal strategy.

As discussed in the proposed rule (80 FR 24460), in support of its assertion that the WATCHMAN® System is a substantial improvement, the applicant submitted data from two pivotal studies (PROTECT AF and the WATCHMAN® Left Atrial Appendage Closure Device in Patients With Atrial Fibrillation Versus Long-Term Warfarin Therapy (PREVAIL)). The data included results of a meta-analysis of the PROTECT AF and PREVAIL studies, an imputed placebo analysis, and a post hoc analysis of the bleeding risks associated with the WATCHMAN® System. According to the applicant, the clinical evidence from these trials and analyses establish the following: implantation of the WATCHMAN® System is safe; the WATCHMAN® System is superior to Warfarin when evaluated against a composite endpoint of all stroke, systemic embolism, and cardiovascular unexplained death in long-term follow-up; the WATCHMAN® System provides a greater reduction in major bleeding events after the conclusion of post procedure anti-thrombotic medication; and the WATCHMAN® System reduces the incidence of ischemic stroke when compared to patients diagnosed with AF who are not treated with Warfarin or other anticoagulation medication.

We note that, unlike in the FY 2015 application, the applicant did not include data from the ASAP study. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28043 through 28045), we expressed concerns that data from the ASAP study suggested that the device did not prevent strokes and was insufficient to demonstrate efficacy in the secondary patient population (patients diagnosed with AF who were ineligible for oral anticoagulation). We specifically stated that the ASAP Registry (5) enrolled 150 patients, at one of four centers, that had a contraindication to even short-term anticoagulation, mostly a history of prior bleeding, and there was no control group. Device implantation led to a serious adverse event in 13 patients (8.7 percent), including one case of device thrombus leading to ischemic stroke. Five other patients had a device-related thrombus that did not lead to stroke (4 of these patients were treated with low molecular weight heparin), resulting in an overall 4.0 percent incidence (6 out of 150) of device-associated thrombus. In the PROTECT AF trial study, 20 of the 473 patients (4.2 percent) had device-associated thrombus, 3 of which led to an ischemic stroke. The rates of device-related thrombus are similar in the two studies (4.0 percent versus 4.2 percent), but the number of patients studied is smaller in the ASAP Registry (5) study compared to the PROTECT AF clinical trial study. In the 14-month follow-up data for the ASAP Registry (5) study, the rate of stroke or systemic embolism was 2.3 percent per year, which was said to be ''lower than expected'' based on prior data for patients diagnosed with AF who were not treated with warfarin (there was no concurrent control group). The data provided suggested efficacy in this patient population. However, we stated that we were concerned that there was not strong evidence that the device prevents stroke.

In the FY 2016 application, the applicant responded that, because the

current intended use and indications for the WATCHMAN® System in the United States do not include patients who are ineligible for treatment using Warfarin therapy, the data from the ASAP study are irrelevant to the FY 2016 application. The applicant provided data from an imputed placebo analysis, a post-hoc analysis that compared the observed rate of ischemic strokes in patients treated with the WATCHMAN® System compared to no therapy, in order to address our concern that there was no strong evidence that the device prevented stroke.

Comment: One commenter, the manufacturer, stated that the ASAP data reflect patients who are intolerant to Warfarin. The commenter stated that it is not seeking coverage for such patients and therefore does not believe that the ASAP data are relevant to the FY 2016 new technology add-on payment application for the WATCHMAN® System and, thus, it was omitted. The commenter noted that patients from the ASAP study are not part of the FDA approved indication. Therefore, the commenter stated that the ASAP registry should not be included in the evaluation for either efficacy or safety. The commenter added that patients eligible for the WATCHMAN® System, although deemed suitable for Warfarin, have a good clinical reason to seek an alternative. The commenter stated that the WATCHMAN® System is not intended as a first line alternative to oral anticoagulation but should be considered in patients for whom the risks of long-term oral anticoagulation outweigh the benefits. The commenter concluded that the appropriate patient population for this application is based on the WATCHMAN clinical trials (PROTECT AF, CAP, PREVAIL, and CAP2).

Response: We thank the commenter for its clarification concerning the appropriate patient population for the WATCHMAN® System.

According to the applicant, in the PROTECT AF trial, 463 patients were randomized to the WATCHMAN® System device and 244 patients to Warfarin therapy. Most patients randomized to the WATCHMAN® System device had it implanted (408=88 percent). Over the average 3.8 years of follow-up, more patients in the Warfarin therapy group withdrew (45 versus 15) or were lost to follow-up (11 versus 13) than in the WATCHMAN® System device group, leading to shorter mean follow-up (3.7 versus 3.9 years) in the Warfarin therapy group.

The applicant presented data shown in the following table and maintained that the results of the PROTECT study demonstrate primary efficacy and support that the WATCHMAN® System is noninferior and superior at 4 years.

TABLE 3—PROTECT PRIMARY EFFICACY SUPPORTS WATCHMAN® NON-INFERIORITY AND SUPERIORITY AT 4 YEARS

Patient years	Years of mean follow-up	WATCHMAN® System observed rate per 100 patient years	Warfarin observed rate per 100 patient years	Percentage reduction vs. warfarin (%)	* Posterior probability		
					Non-inferiority (NI) (%)	Superiority (S) (%)	
1065	1.5	3	4.9	38	>99.9	90.00	NI.
1588	2.3	3	4.3	29	>99.9	84.60	NI.
2621	3.8	2.3	3.8	40	>99	96	NI and S.
2717	4	2.2	3.7	39	>99.9	95.40	NI and S.

* For Bayesian analysis, a posterior probability of 97.5 percent represents non-inferiority; ≥95 percent represents superiority.

In the FY 2015 IPPS/LTCH PPS proposed rule, we expressed concern that the evidence presented by the applicant demonstrating superiority compared to Warfarin therapy was insufficient. We expressed concern that the PROTECT AF trial was not designed to demonstrate superiority, and instead was designed to demonstrate noninferiority. We also expressed concern that the PREVAIL trial endpoint was not significantly improved in the conventional hypothesis testing statistical analysis at any time point. We stated that the longer term data showed improved efficacy and safety, but still remain sparse. In the FY 2016 application, the applicant stated that, under a Bayesian analysis, the distributions of the posterior probabilities are not symmetrical. According to the applicant, posterior probabilities represent the appropriate way to determine statistical significance in Bayesian methodology. As predefined in the PROTECT AF trial, a posterior probability for noninferiority of equal to or more than 97.5 percent, and a prespecified level of at least 95 percent to support superiority were the criteria for statistical testing. According to the applicant, in both cases (noninferiority and superiority), the criteria were met for long-term follow-up as demonstrated in the results of the PROTECT AF trial. In the proposed rule, we stated that we agreed that the Bayesian methodology is a valid method of analysis. However, we were referencing the overall efficacy noninferiority in the PREVAIL trial.

In the FY 2016 proposed rule (80 FR 24461), we again presented our continued concern that the data results from the PROTECT AF study are insufficient to show superiority of the WATCHMAN® System over Warfarin therapy. We noted that the study was unblinded with a noninferiority design. We stated that we believe that the reduction in cardiovascular mortality shown in the results from the PROTECT AF study was unexpected and not well explained. Among the 57 patients in the WATCHMAN® System group who died, only 53 patient cases were assigned a cause of death and only 5 of the 9 ''unexplained/other deaths'' were included in the primary endpoint, although the protocol established that unexplained deaths were to be considered as cardiovascular mortalities. The total number of ''cardiovascular or unexplained deaths'' would have been 21, not 17. In the Warfarin therapy group, there was 1 ''unexplained/other'' death that should have been included in the primary endpoint, resulting in a total of 23, not 22. We acknowledged that it may be difficult to calculate the impact of these additional events as the intention-to-treat analysis of the primary endpoint. However, we stated our concern that the inclusion of the additional deaths could have made the posterior probabilities for the device less favorable. Based on the data at face value, we stated that it appears that the WATCHMAN® System does not demonstrate statistically significant superiority over treatment with Warfarin therapy until 3.8 years has elapsed and the patient has been administered 6 months of oral anticoagulation and been exposed to the risk of the device-related complications. We stated that we were concerned that the applicant has not demonstrated

substantially improved clinical outcomes.

In the prospective randomized evaluation of the PREVAIL study, the goal was to assess the safety and efficacy of LAA occlusion for stroke prevention in patients diagnosed with NVAF compared to long-term Warfarin therapy. The PREVAIL study was a confirmatory randomized trial designed to further assess the efficacy and safety of the WATCHMAN® System device. Patient selection and study design were similar to the PROTECT AF study. Two efficacy and 1 safety coprimary endpoints were assessed at 18 months. The rate of the first coprimary efficacy endpoint overall efficacy (composite of stroke, systemic embolism [SE], and cardiovascular/unexplained death) was 0.064 in the WATCHMAN® System device group versus 0.063 in the control group (rate ratio 1.07 [95 percent credible interval (CrI) 0.57 to 1.89]) and did not achieve the prespecified criteria of noninferiority (upper boundary of 95 percent CrI 1.75). The rate for the second coprimary efficacy endpoint (stroke or SE >7 days' post-randomization) was 0.0253 versus 0.0200 (risk difference 0.0053 [95 percent CrI –0.0190 to 0.0273]), which achieved noninferiority. Early safety events were significantly lower than the results of the PROTECT AF study, which satisfies the prespecified safety performance goal. The PREVAIL study was designed to demonstrate noninferiority with wide efficacy margins. However, as previously stated, our concern was that the results of the study did not show the overall efficacy of the technology to be noninferior.

Comment: The applicant responded to our concerns and commented that it appreciates that CMS agrees that the Bayesian approach is valid for analyzing PROTECT AF and PREVAIL trials as both were powered based on those statistics. Although CMS agrees with this approach, the applicant asserted that it appears contradictory also to judge PREVAIL efficacy using a frequentist approach. The applicant stated that the primary objective of PREVAIL was to confirm procedural safety due to early complications from the first half of PROTECT AF. The applicant noted that, although the procedural complication rates were reduced by approximately 50 percent in the second half of PROTECT AF, and were maintained in the CAP registry, the FDA required the applicant to perform a second randomized trial to confirm this improvement in safety. The applicant stated that PREVAIL was the confirmatory trial that demonstrated the safety profile of the WATCHMAN® System and showed the device could be safely implanted by both experienced and new operators.

The applicant acknowledged that when the efficacy data are considered on their own, the WATCHMAN® arm in PREVAIL missed both co-primary efficacy endpoints (the 18-month rates of the composite of stroke (including hemorrhagic or ischemic), systemic embolism, and cardiovascular or unexplained death and the 18-month rates of ischemic stroke or systemic embolism excluding the first 7 days post-randomization) in the October 2014 updated post hoc analyses. The applicant stated the reason why the stand-alone data in PREVAIL missed overall efficacy was due in large part to the over-performance of the Warfarin arm in PREVAIL. The applicant noted that when evaluating the Warfarin arm in PREVAIL, with respect to ischemic strokes, it outperformed historical Warfarin trials (and real-world experience) and the assumptions used for the design of the PREVAIL trial. Specifically, the applicant noted that the rate of ischemic strokes was three times less than any Warfarin control trial in the last decade, with an annual rate of 0.3 percent for ischemic stroke [62] compared with 1.05 to 1.42 percent in other trials of oral-anticoagulant trials that included over 29,000 Warfarin patients.[63] [64] [65] [66] In addition, the applicant stated the following: That although the PREVAIL ischemic stroke rate in the WATCHMAN® arm was numerically higher than the Warfarin arm, it was consistent with the long-term follow up of all WATCHMAN® patients in all other trials; the ischemic stroke rates for the WATCHMAN® group are similar to those treated with anticoagulants as seen in PROTECT AF and the CAP registry when accounting for the higher CHA_2DS_2–VASc score. The applicant indicated that this implies the rates of ischemic stroke in the WATCHMAN® arm of the PREVAIL trial are comparable to those with treated with anticoagulants and shows a similar benefit as compared to Warfarin.[67]

The applicant further noted that although the PREVAIL efficacy endpoints were missed, the data was consistent with demonstrating non-inferiority (93 percent posterior probability of non-inferiority) of WATCHMAN® compared to Warfarin and came close to achieving statistical proof of non-inferiority (that is, posterior probability of 95.69 percent) with respect to the primary efficacy endpoint of composite stroke, systemic embolism and cardiovascular death.

The applicant also noted that in the primary December 2013 analysis specified by the protocol (using data locked in January 2013), the Bayesian estimate for the 18-month rate ratio was 1.07 with a 95 percent credible interval of 0.57 to 1.89. The applicant stated that the upper bound of 1.89 was not lower than the non-inferiority margin of 1.75 defined in the statistical analysis plan, the non-inferiority criterion was not met in the pre-specified analysis (the posterior probability of non-inferiority was 95.69 percent). In the ad hoc October 2014 Bayesian analysis (using data locked in June 2014), the applicant noted that the 18-month rate was 0.065 for the Device group and 0.057 for the Control group. Also, the Bayesian estimate for the 18-month rate ratio was 1.21 with a 95 percent credible interval of 0.69 to 2.05. The applicant stated that because the upper bound of 2.05 was not lower than the non-inferiority margin of 1.75 defined in the statistical analysis plan, the non-inferiority criterion was still not met (the posterior probability of non-inferiority was 92.6 percent).

The applicant stated that the second primary endpoint evaluated the post-procedure difference between the WATCHMAN® System and Warfarin in terms of ischemic stroke and systemic embolism. The applicant noted the following: In the December 2013 data (using the January 2013 data lock), the pre-specified primary analysis time point, the 18 month rate difference was 0.0053, with a posterior probability of non-inferiority of 97.6 percent with the device meeting its endpoint; in October 2014, an updated analysis was performed on a data set locked in June 2014 where the rate difference increased to 0.0163 due to additional ischemic

[62] Holmes *et al.* Prospective randomized evaluation of the Watchman left atrial appendage Device in patients with atrial fibrillation versus long-term warfarin therapy; the PREVAIL trial. *JACC,* Vol. 4, No. 1, 2014, 1–11.

[63] Patel MR and the ROCKET AF Steering Committee for the ROCKET AF Investigators. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med.* 2011;365(10):883–891.

[64] Granger CB and the ARISTOTLE Committees and Investigators. Apixaban versus warfarin in patients with atrial fibrillation. *N Engl J Med.* 2011;365(11):981–992.

[65] Connolly SJ, Ezekowitz MD, Yusuf S, *et al.* and the RE–LY Steering Committee and Investigators. Dabigatran versus warfarin in atrial fibrillation patients. *N Engl J Med.* 2009;361:1139–51.

[66] Giugliano, R.P., C.T. Ruff, *et al.* (2013). ''Edoxaban versus Warfarin in Patients with Atrial Fibrillation.'' *New England Journal of Medicine* 369(22): 2093–2104.

[67] Friberg L. *et al.* Evaluation of risk stratification schemes for ischaemic stroke and bleeding in 182,678 patients with atrial fibrillation: the Swedish Atrial Fibrillation cohort study. *Eur Heart J* (2012). *NICE UK* (2014).

stroke events; the upper bound crossed the pre-specified boundary of 0.0275 resulting in the endpoint being missed with a posterior probability of non-inferiority of 89.2 percent. The applicant stated that the WATCHMAN® arm of PREVAIL was performing similarly to the other trials and the additional ischemic strokes aligned with the stroke risk over longer term follow up in the PROTECT trial.

The applicant noted that the PROTECT AF trial provided the informative prior for PREVAIL under the Bayesian analysis. The applicant stated that the total number of patients and duration of follow-up in PROTECT far exceeds that of PREVAIL as PROTECT AF represents over 75 percent of the randomized patient follow-up data, while PREVAIL accounts for less than a quarter.

For long-term performance of WATCHMAN®, the applicant stated that CMS should evaluate the primary efficacy data from PROTECT AF where patients have completed 2,717 patient years of follow up (compared to PREVAIL at 860 patient years) and have consistently demonstrated non-inferiority to Warfarin and shown superiority at 2,621 patient years. The applicant noted that, although PROTECT AF was not designed to show superiority of WATCHMAN® to Warfarin, as it was designed to be a non-inferiority trial, it was also designed to have the potential to demonstrate superiority. The applicant noted that while the protocol allowed for testing of superiority provided that non-inferiority was shown, the lack of power to show superiority means that the study was not likely to demonstrate superiority given the sample size and expected performance of WATCHMAN® vs. Warfarin.

The applicant also noted the following: Although the 95 percent posterior probability of superiority does not cross the boundary until the 3.8 year time point, the data are consistent with superiority as early as the 1.3 year (900 patient year) analysis; the rate ratio is relatively constant thereafter, reflecting consistency of the benefit of WATCHMAN® versus Warfarin from that point onward.

The applicant also provided data from a patient level meta-analysis that combined the PROTECT AF and PREVAIL data to support the efficacy of the WATCHMAN® System and show the device was performing as expected when compared to the Warfarin control arm. The applicant stated the following major results from the meta-analysis of the PROTECT AF and PREVAIL randomized studies:

- Primary Efficacy Endpoint: The WATCHMAN® System was associated with a 21 percent reduction in the risk of a primary efficacy endpoint event, though not statistically significant (p=0.23).
- Stroke and Systemic Embolism: The WATCHMAN® System is similar to Warfarin in preventing all-cause stroke and systemic embolism (HR=1.02, p=0.93). It is associated with a decrease in the relative risk of hemorrhagic stroke (88 percent, p=0.004); however, the device is not as effective as Warfarin in reducing the risk of ischemic stroke (HR=1.96, p=0.049). The applicant stated that in considering the total risks and benefits of the WATCHMAN® System, it is important to take into account more than the ischemic stroke event such as comparison of stroke severity (hemorrhagic versus ischemic), major bleeds, and mortality.
- Stroke Severity: Using the mRS instrument, those strokes occurring in the WATCHMAN® device arms were significantly less likely to be disabling (49 percent relative reduction in disabling strokes, p=0.044) than those occurring in the Warfarin groups.
- Major Bleeds: Warfarin can cause bleeding in anatomic locations other than the brain, such as the eye or spine. When considering all major bleeds unrelated to the implant procedure, Warfarin was associated with an approximately two-fold relative increase in the risk of a major bleed (p=0.002).
- Mortality: Use of the WATCHMAN® System is associated with a 27 percent relative reduction in the risk of all-cause mortality, though not statistically significant (p=0.074) and a 52 percent relative reduction in the risk of cardiovascular (CV)/unexplained mortality (p=0.006).

The applicant stated that the primary efficacy endpoint for each of the trials included cardiovascular (or unexplained) death, all strokes (both ischemic and hemorrhagic) and systemic embolism. Of the components of this endpoint, the commenter stated that death is the most devastating, followed in importance by hemorrhagic strokes (which are generally catastrophic and typically result in greater disability than ischemic strokes). Therefore, when interpreting the patient-level meta-analyses, the applicant asserted that the overall conclusion is that the WATCHMAN® System is a reasonable alternative to Warfarin. The applicant noted that use of the WATCHMAN® System did not change the overall rate of all-cause stroke, but it did alter the proportion of stroke subtypes: There was a reduction in hemorrhagic stroke which was offset by less effective prevention of ischemic stroke. The applicant also noted the following: Although the overall rate of all-cause stroke was unchanged, patients with the WATCHMAN® System were significantly less likely to have a disabling stroke; when compared to Warfarin, the WATCHMAN® System yielded a significant relative reduction in the risk of major bleeding by 51 percent as well as a significant relative reduction in the risk of mortality due to CV or unknown causes by 52 percent;[68] while the rates of all-stroke in the meta-analysis were the same between groups (HR=1.02, p=0.94), the rate of ischemic strokes was less in the Warfarin arm (HR=1.95, p=0.05) while the rate of hemorrhagic strokes was much less in the WATCHMAN® arm (HR=0.22, p=0.004).

The applicant stated the following conclusions: While PREVAIL was never intended nor powered to stand-alone for demonstrating overall efficacy, the primary purpose was to demonstrate procedural safety; although the PREVAIL primary efficacy endpoint was missed, CMS should not judge overall efficacy of the WATCHMAN® System in the absence of the long-term follow-up data from PROTECT AF and the meta-analysis which provides a more complete picture of the data showing that WATCHMAN® efficacy outcomes are similar to those of Warfarin in patients who do not take oral anticoagulants; the WATCHMAN® System performance was consistent across trials and the additional ischemic strokes seen over time in PREVAIL align appropriately with the higher stroke risk scores in this trial (that is, patients with mean $CHADS_2$ scores ranging from 2.2 to 2.7 in the consecutive trials, and CHA_2DS_2–VASc scores from 3.5 to 4.5, with the majority of patients in all trials considered high risk and anticoagulation recommended per AHA/ACC/HRS guidelines).

Response: We thank the applicant for the additional information and clarifications. We also appreciate the additional meta-analysis which we considered in our decision below. However, we continue to be concerned that the 95 percent posterior probability of superiority is not met for a number of years. In addition, there is no data establishing sustained effectiveness and superiority long term.

Comment: With regard to CMS' interpretation of CV unexplained death,

[68] Holmes DR, Jr., Doshi SK, Kar S, *et al.* Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation: A Patient-Level Meta-Analysis. *J Am Coll Cardiol.* 2015;65(24):2614–2623. doi:10.1016/j.jacc.2015.04.025. (*In Press*).

one commenter clarified that all four studies employed an independent Clinical Events Committee (CEC) to review and adjudicate site-reported adverse events and ascertain their seriousness, relationship of the event to the device or procedure, and relationship of study medications to the study endpoints.[69] The commenter stated that the four deaths questioned by CMS were adjudicated by this independent committee and were assigned to the correct mortality categories. The commenter also noted that there are two mortality categories with the word ''other'': ''Cardiovascular—Unexplained/other'' and ''Other (Non-Cardiovascular)''. The commenter explained that for determining the appropriate category, if a specific cause of death could not be determined, the death was assigned conservatively to the ''Cardiovascular—Unexplained/other'' category and it was factored into the PROTECT AF primary efficacy endpoint and if the cause of a death was known but not cardiovascular-related, such as suicide or motor vehicle accident, then the death was assigned to the ''Other (Non-Cardiovascular)'' category. The commenter stated that CMS is incorrectly implying that the four deaths assigned in the ''Other (Non-Cardiovascular)'' category should be included in the ''Cardiovascular—Unexplained/other'' category. The commenter explained that such an interpretation is incorrect because the causes of these deaths were known and determined not to be cardiovascular-related.

Response: We thank the commenter for clarifying and resolving our concern with regard to CV unexplained death and how these deaths were classified into either the ''Cardiovascular—Unexplained/other'' or ''Other (Non-Cardiovascular)'' category.

As discussed in the proposed rule (80 FR 24462), the applicant submitted data from a patient-level meta-analysis that combined the data from the PROTECT AF study with the data from the PREVAIL study. According to the applicant, this analysis supports the efficacy of the WATCHMAN® System and shows that the device was performing as expected compared to the Warfarin therapy control arm. The datasets were combined and weighted. According to the applicant, multiple outcomes of interest were examined, starting with the primary efficacy endpoint and then looking at individual outcomes: All stroke (ischemic and hemorrhagic) and associated disability; systemic embolism; cardiovascular/unexplained death; and major bleeding. The overall incidence of all strokes (ischemic and hemorrhagic) was not statistically different between the WATCHMAN® System arm and the Warfarin therapy arm. However, the applicant stated that there were statistical differences identified when it analyzed the stroke subtypes. The applicant indicated that, initially, there were more ischemic strokes in the WATCHMAN® System arm. However, after accounting for early procedural complications, including strokes (within 7 days post procedure) in the PROTECT AF study, the difference for ischemic stroke between the two arms fell below statistical significance (p=0.21). According to the applicant, there were significantly more hemorrhagic strokes and cardiovascular deaths in the Warfarin therapy arm compared to the WATCHMAN® System arm, showing a 78 percent and 52 percent reduction in those events respectively (p=0.004 and p=0.006). To better assess the clinical impact of the different subtypes of strokes on patients, the applicant also performed statistical tests on disabilities resulting from stroke. The applicant indicated that, using a validated stroke severity assessment tool (Modified Rankin score), analyses show that there were significantly less disabling strokes with the WATCHMAN® System than Warfarin therapy. The applicant believed that this represents a substantial clinical improvement for the WATCHMAN® System device.

The applicant conducted an imputed placebo analysis to assess the benefit that untreated patients may expect with the WATCHMAN® System device. The applicant contended that many patients who are eligible for Warfarin therapy are not receiving any treatment and, therefore, are left unprotected from stroke. With annual ischemic stroke rates ranging from 5.6 percent to 7.1 percent, the applicant maintained that the WATCHMAN® System device provides a substantive clinical benefit. In order to assess the benefit that untreated patients may be able to expect with the WATCHMAN® System, the sponsor performed the following exploratory analysis. The observed device ischemic strokes rates were compared against the estimated stroke risk of untreated nonvalvular AF patients. A placebo arm was then constructed using ''well-established, validated literature'' models based on both the $CHADS_2$ and $CHA2DS_2$–VASc scores. The applicant reported that this analysis showed the WATCHMAN® System device reduced stroke in the untreated patient population by 65 to 81 percent.

In the proposed rule, we noted that we previously expressed concern that there was a lack of strong evidence demonstrating that the WATCHMAN® System prevents stroke at all. The applicant responded that the imputed placebo analysis cited above addresses this concern. The applicant provided the table below as part of its FY 2016 application to show the relative risk reduction in Ischemic stroke rates using the WATCHMAN® System versus no therapy.

TABLE 5—WATCHMAN® SHOWS SIGNIFICANT REDUCTION IN ISCHEMIC STROKES COMPARED TO NO THERAPY

Study	Average CHADS (2 footnote on acronym) score WATCHMAN® patients	Observed WATCHMAN® annual ischemic stroke rate (95 Percent CI)	Imputed untreated annual event rate	Relative risk reduction
PROTECT AF	2.2	1.3 (0.9, 2.0)	5.6 to 5.7	77% (64%, 84%)
PREVAIL-only	2.6	2.3 (1.3, 4.0)	6.6 to 6.7	65% (39%, 80%)
CAP	2.5	1.2 (0.8, 1.8)	6.4	81% (72%, 88%)

While the results of this analysis appear to suggest a large reduction in ischemic stroke rates in patients who did not receive any treatment, we continued to have some concerns regarding whether the WATCHMAN®

[69] The Establishment and Operation of Clinical Trial Data Monitoring Committees for Clinical Trial Sponsors; Guidance for Clinical Trial Sponsors—Establishment and Operation of Clinical Trial Data Monitoring Committees, issued March 2006.

System device prevents strokes. The indication for the treatment of the WATCHMAN® System device is for patients who are eligible for Warfarin therapy as opposed to patients who are ineligible for Warfarin therapy. We stated that our concern is that the results of the imputed placebo analysis are not sufficient to determine whether the WATCHMAN® System reduces the risk of stroke in patients who are eligible for Warfarin therapy. The applicant suggested that patients who are subtherapeutic or noncompliant with Warfarin therapy would have the same risk of stroke as patients who do not receive any therapy. However, the applicant did not offer any evidence that these two groups have the same risk of stroke. The WATCHMAN® System device is intended only for use in patients who are eligible for the anticoagulation, not for patients who have contraindications to oral anticoagulation. Because the device will not be labeled for use in those patients, we stated in the proposed rule that we believe that an analysis comparing stroke risk of untreated patients to those patients treated with the WATCHMAN® System is of limited value in assessing the technology's benefit over existing therapy.

Comment: The applicant commented and explained that the imputed placebo analysis compares patients enrolled in the WATCHMAN® trials to similar patients from large real-word databases. The applicant noted that a placebo arm was constructed using well-established, validated literature models based on both the $CHADS_2$ and CHA_2DS_2–VASc scores. The applicant stated that a benefit was then imputed, through analysis of the WATCHMAN® trials, for the WATCHMAN® System as compared to the imputed placebo patients, and a relative reduction in events was computed. The applicant clarified that this imputed placebo comparison is to ''untreated'' Warfarin-eligible non-valvular AF patients and not to patients contra-indicated or ineligible for Warfarin as the majority of these ''untreated patients'' are eligible for Warfarin and were not contraindicated for Warfarin. The applicant noted that when compared to untreated patients, each of the WATCHMAN® studies is associated with a substantial reduction in the risk of ischemic stroke, demonstrating a consistent and clinically meaningful response across each study. The applicant further noted that stroke risk reduction is between 65 and 81 percent when comparing the performance of the WATCHMAN® System to the groups used in the imputed placebo analyses.[70] The applicant concluded that imputed placebo analyses show there is a strong expectation of a beneficial effect of WATCHMAN® when applied as intended to the patients who are eligible for Warfarin for the short-term but who are unable or unwilling to take the drug for the long-term and who would otherwise go untreated.

Response: We thank the applicant for the additional input. We considered these comments in our decision below.

As discussed in the proposed rule (80 FR 24463), the applicant asserted that one of the primary goals of mechanical LAA closure is to provide an alternative treatment for patients other than long-term Warfarin therapy and exposure to the associated risk for bleeding. Although the primary efficacy endpoint of the PROTECT AF and PREVAIL studies considered hemorrhagic stroke, it did not encompass other types of major bleeding that may be associated with the use of Warfarin. The applicant indicated that it performed a supplemental analysis to determine the relative risks of all types of bleeding. The applicant divided the follow-up interval into four subsections (7 days, 45 days, 6 months, and 54 months). The applicant compared bleeding events in the WATCHMAN® System arm with the Warfarin therapy arm and concluded that, after 6 months (and discontinued use of Clopidogrel in the WATCHMAN® System group), the continued use of Warfarin was associated with a 3.4 fold increase in the risk of major bleeding. According to the applicant, the significant reduction in bleeding after the procedural and concomitant medication therapy (6 months) with the cessation of long-term anticoagulants illustrates the substantial clinical benefit of the WATCHMAN® System. However, given the high burden endured (most notably, the higher risk of bleeding occurring in the first 7 days of an inpatient hospital stay) to achieve a reduction in bleeding in the long term, we stated in the proposed rule that we do not believe the WATCHMAN® System meets the criteria for substantially improved clinical outcomes. In the proposed rule, we invited public comments on whether this technology meets the substantial clinical improvement criterion, particularly in light of the applicant's response to our previous concerns and our current concern that there remains insufficient evidence that the WATCHMAN® System substantially improves clinical outcomes in patients diagnosed with nonvalvular AF and who are eligible for Warfarin therapy.

Comment: The applicant commented that despite WATCHMAN® System overall positive safety profile, CMS is choosing one specific event rate (that is, risk of peri-procedural bleeding) to conclude that WATCHMAN® System does not meet the criteria for substantial clinical improvement. The applicant argued that any device implant has some peri-procedural risks associated with the procedure (that is, pacemakers, defibrillators), but this should be balanced with the long-term risks of not having the therapy available (for example, death). The applicant stated that as long as the potential device safety profile is well established in well-designed clinical trials and the risks are within the norms of other established device-based therapies, FDA approved treatment options should be eligible for consideration as a substantial improvement over available alternatives; this is especially true when the long-term risks of those alternatives, in this case non-treatment with long term oral anticoagulation, are high. The applicant noted that, in this regard, incidence of safety events fell from 9.9 percent in the first half of PROTECT AF to 4.8 percent in the second half after changes were made in operator training and technical aspects of the procedure. The applicant also noted that the reduction in safety events was evident in the CAP Registry where the safety event was 4.1 percent; the PREVAIL trial where the event rate was 2.2 percent with a 95 percent credible interval bound of 2.65 percent, within the pre- specified performance goal of 2.67 percent and in the CAP2 registry where the safety event remained constant around 4.1 percent. The applicant noted that the WATCHMAN® procedural risks are on par with most left atrial cardiovascular medical device interventions (for example, ablation).[71]

The applicant also noted the following: The one-time 7-day peri-procedural WATCHMAN® complication rate of 3.8 to 4.1 percent is similar to the yearly frequency of major bleeding or intracranial hemorrhage for patients on long-term Warfarin, which is 3.1 to 3.6 percent;[72] [73] [74] [75] that any sequelae

[70] Hanzel G, Almany S, Haines D, Berman A, Huber K, Kar S, Holmes D. Comparison of Imputed Placebo Versus Observed Ischemic Stroke Rates in the WATCHMAN Trials Represents a Significant Reduction in Risk (TCT2014 Presentation #176).

[71] Boston Scientific FDA Panel October 2014.

[72] Patel MR and the ROCKET AF Steering Committee for the ROCKET AF Investigators. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med.* 2011;365(10):883–891.

[73] Granger CB and the ARISTOTLE Committees and Investigators. Apixaban versus warfarin in

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associated with the upfront bleeding risks associated with the implant procedure, unlike those that occur in patients on long-term Warfarin, should be more effectively managed because they occur in-hospital under medical supervision where immediate treatment is available.

The applicant also stated that CMS' analysis does not consider that the bleeding rate with oral anticoagulation therapy is compounded yearly (that is, the risk goes up with longer exposure to Warfarin), dramatically increasing the likelihood of hemorrhagic stroke. The applicant asserted that, in contrast, WATCHMAN® patients are free of the burden of life-long treatment with Warfarin (99 percent Warfarin cessation at 12 months in PREVAIL and CAP2) and the bleeding risk is constant and reduced in years 1–9 post implant. The applicant stated that the reduced bleeding benefits associated with the WATCHMAN® System continue to diverge from Warfarin outcomes and the magnitude of benefit increases over time.[76] Furthermore, the applicant asserted that for patients with CHA_2DS_2VASC score of 2 or greater, who are not on long-term oral anticoagulation and are unprotected against ischemic stroke, the annual risk of stroke ranges from 2 to 24 percent and over a 5-year period, the risk is between10 to 75 percent that these patients may experience an ischemic stroke.

Response: While we agree with the commenter that one specific event rate (that is, risk of peri-procedural bleeding) should not preclude the WATCHMAN® System from meeting the criteria for substantial clinical improvement, we continue to be concerned that the 95 percent posterior probability of superiority is not met for a number of years. In addition, there is no data establishing sustained effectiveness and superiority long term. While the WATCHMAN® System can be an alternative to the subset of patients with nonvalvular atrial fibrillation who are unable to tolerate warfarin long term, we are concerned that the WATCHMAN® System is not as effective as Warfarin in reducing the risk of ischemic stroke.

Also, the clinical trials compared the WATCHMAN® System to Warfarin. Other anti-coagulants may be an effective treatment for this small population not eligible for Warfarin. Without additional clinical data, we are unable to determine if patients who respond to other anti-coagulants would require the WATCHMAN® System. Therefore, based on the reasons stated above, we do not believe that the WATCHMAN® System meets the substantial clinical improvement criteria at this time and are not approving the WATCHMAN® System for new technology add on payment for FY 2016. We welcome the applicant to reapply next year as additional long-term data becomes available.

Comment: Many commenters supported the approval of the WATCHMAN® System for new technology add-on payment for FY 2016. Many of the commenters spoke about their experience with the device and reiterated many of the points expressed by the applicant in its comments.

Response: We thank the commenters for their comments. However, as mentioned above, we are not approving the WATCHMAN® System for new technology add-on payment for FY 2016.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2016 hospital wage index based on the statistical areas appears under sections III.A.2. and G. of the preamble of this final 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. 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 adjustment for FY 2016 is discussed in section II.B. of the Addendum to this final rule.

As discussed in section III.J. of the preamble of this final 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 budget neutrality adjustment for FY 2016 is discussed in section II.A.4.b. of the Addendum to this final 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 applying, beginning October 1, 2015 (to the FY 2016 wage index), appears under sections III.E.3. and F. of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) for the FY 2016 Final Rule

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). 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, and provided guidance on the use of the delineations of these statistical areas based on new standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and the 2010 Census of Population and Housing data (we refer to these revised OMB delineations as the ''new OMB delineations'' in this final rule). A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13–*

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patients with atrial fibrillation. *N Engl J Med.* 2011;365(11):981–992.

[74] Connolly SJ, Ezekowitz MD, Yusuf S, et al and the RE–LY Steering Committee and Investigators. Dabigatran versus warfarin in atrial fibrillation patients. *N Engl J Med.* 2009;361:1139–51.

[75] Giugliano, R.P., C.T. Ruff, et al. (2013). ''Edoxaban versus Warfarin in Patients with Atrial Fibrillation.'' *New England Journal of Medicine* 369(22): 2093–2104.

[76] Boston Scientific WATCHMAN FDA Panel Sponsor Presentation—October 2014.

01.pdf. 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 new OMB labor market area delineations for the FY 2015 wage index. For FY 2016, we are continuing to use the new OMB delineations that we adopted beginning with FY 2015 to calculate the area wage indexes, including the transition wage indexes, which we discuss below.

B. Worksheet S–3 Wage Data for the FY 2016 Wage Index

The FY 2016 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2012 (the FY 2015 wage indexes were based on data from cost reporting periods beginning during FY 2011).

1. Included Categories of Costs

The FY 2016 wage index includes 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 includes 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 47318)); 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 2015, the wage index for FY 2016 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 FY 2016 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 FY 2016 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10) for cost reporting periods beginning on or after October 1, 2011, and before October 1, 2012. For wage index purposes, we refer to cost reports during this period as the ''FY 2012 cost report,'' the ''FY 2012 wage data,'' or the ''FY 2012 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 FY 2016 wage index includes FY 2012 data submitted to us as of June 29, 2015. 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 2016 wage index, we identified and excluded 93 providers with aberrant data that should not be included in the wage index. We stated in the FY 2016 IPPS/LTCH PPS proposed rule that if data elements for some of these providers with aberrant data are corrected, we intended to include data from those providers in the final FY 2016 wage index (80 FR 24464). We also adjusted certain aberrant data elements within a provider's 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 contract housekeeping and dietary services, we imputed estimates, in accordance with established policies as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We stated that we intended to resolve all unresolved data elements by the date the FY 2016 IPPS/LTCH PPS final rule is issued. The revised data are reflected in this FY 2016 IPPS/LTCH PPS final rule.

As a result of further review by the MACs and the April and June appeals processes, we received corrected data or improved documentation for 34 hospitals, and therefore, we are including these 34 hospitals in the final FY 2016 wage index. The hospitals that are excluded from the wage index remain excluded for a variety of reasons, such as, but not limited to, unresponsiveness to requests for documentation or insufficiently documented data, terminated hospitals' failed edits for reasonableness, or low Medicare utilization.

In constructing the proposed FY 2016 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2012, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe 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). For the FY 2016 IPPS/LTCH PPS proposed rule, we removed 12 hospitals that converted to CAH status on or after February 13, 2014, the cut-off date for CAH exclusion from the FY 2015 wage index, and through and including February 5, 2015, the cut-off date for CAH exclusion from the FY 2016 wage index. After issuance of the proposed rule, we learned of one more hospital that converted to CAH status on or after February 13, 2014, and through and including February 5, 2015. Therefore, for this FY 2016 IPPS/LTCH PPS final rule, we removed a total of 13 CAHs that converted to CAH status on or after February 13, 2014, and through and including February 5, 2015. After removing hospitals with aberrant data and hospitals that converted to CAH status, we calculated the final FY 2016 wage index based on 3,362 hospitals.

For the final FY 2016 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 2015 wage index (79 FR 49964). Table 2, which contains the final FY 2016 wage index associated with this final rule (available via the Internet on the CMS Web site), includes separate wage data for the campuses of 8 multicampus hospitals. (We note that, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24464), we indicated that the proposed Table 2 includes separate wage data for the campuses of 7 multicampus hospitals. At the time of the development of the proposed rule, we were unaware of one additional multicampus hospital. We have included this eighth multicampus hospital in the FY 2016 final wage index.)

Comment: Commenters disagreed with the exclusion of certain hospitals' data from the FY 2016 wage index public use files (PUFs) and requested that these hospitals be included in the FY 2016 final rule. The commenters asked for transparency and disclosure of criteria for these hospitals' exclusion. They noted that the number of hospitals excluded from the wage index has risen over past years and that it is especially important for CMS to make decisions in a reasoned, consistent, and transparent manner because the entire CBSAs' average hourly wages are impacted by deleting one hospital with a higher average hourly wage. The commenters noted that 93 hospitals were deleted from the FY 2016 proposed wage index, as compared to only 49 hospitals that were deleted from the FY 2015 proposed wage index. The commenters questioned CMS' statutory authority to exclude data from hospitals with higher than average labor costs, and argued that section 1886(d)(3)(E) of the Act cannot be read to support the agency's position that it has the discretion to delete certain hospitals from the PUF if they have extremely high labor costs. The commenters asserted that removal of these hospitals' data is ''arbitrary and capricious'' and an ''abuse of discretion.'' The commenters also asserted that CMS should prove that a hospital's costs are abnormal, and argued that, without giving hospitals advanced notice or guidance through a notice and public comment process as to what would make their costs qualify as ''excessive'' or ''unusual,'' hospitals cannot modify their practices to avoid such a determination. The commenters further reasoned that CMS' decision to exclude certain hospitals' data undermines the MAC desk review process, and therefore, it is inappropriate to ask hospitals to defend their data post-audit.

One commenter representing hospitals located in CBSA 46140, where a hospital was excluded due to having a very high average hourly wage relative to the CBSA, disagreed with the removal of the wage data of that hospital from the FY 2015 and FY 2016 wage indexes, and argued that ''if CMS were to adopt a policy of excluding the hospital with the highest wage data from each CBSA, fairness would require that CMS also exclude the hospital with the lowest wage data from each CBSA.'' The commenter stated that hospitals are aware of no such CMS policy.

Commenters asked for improved CMS communication with hospitals, including enlisting the MACs to notify hospitals in writing if the hospitals are excluded from the PUF, the criteria used to determine whether a hospital was excluded, and the procedures that a hospital may use to ask for reconsideration. The commenters also suggested that MACs be directed to notify State hospital associations not only when hospitals do not respond during the desk review, but also when there are efforts underway to correct hospitals' aberrant data.

Response: 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 area of the hospital compared to the national average hospital wage level. We believe that, under this section of the Act, we have discretion to exclude aberrant hospital data from the wage index PUFs to help ensure that the costs attributable to wages and wage-related costs in fact reflect the relative hospital wage level in the hospitals' geographic area.

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. Hospitals are aware that both the MACs (via instructions issued by CMS) and CMS evaluate the accuracy and reasonableness of hospitals' wage index data, and hospitals may appeal to CMS as part of the April and June appeals processes. 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 the MACs and, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. Each year, in the IPPS proposed rules, we discuss the process wherein CMS asks the MACs to ''revise or verify data elements that result in specific edit failures'' (80 FR 24464). In the FY 2016 IPPS/LTCH PPS proposed rule, similar to the proposed rules of prior years, we stated that we included the wage data for facilities that were IPPS hospitals in FY 2012, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is appropriate, in general, to reflect 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 (80 FR 24464). That is, a hospital is included in the wage index if its data are reasonable, regardless of whether the hospital is open or whether it has terminated after the relevant past period, because the wage index is constructed to represent the relative average hourly wage for each labor market area in that past period. Thus, reasonableness and relativity to each area's average hourly wages have been longstanding tenets of the wage index development process that CMS has articulated in rulemaking.

We disagree with the commenters that removing hospitals from the FY 2016 wage index PUFs was arbitrary and undermined the MAC desk review process because, as discussed above, as a standard part of the refinement of the annual wage index, CMS evaluates the wage data for both accuracy and reasonableness to ensure that the wage index is a relative measure of the labor value provided to a typical hospital in a particular labor market area. As part of this evaluation process, it is CMS, not the MACs, that makes the decisions to include or exclude a hospital's data from the wage index, and it would not be appropriate for CMS to make such decisions prior to a desk review being performed. The commenters seem to indicate that only hospitals with high average hourly wages were removed from the PUFs, noting that 93 hospitals were deleted from the FY 2016 proposed wage index, as compared to only 49 hospitals that were deleted from the FY 2015 proposed wage index. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24464), we stated that ''For the proposed FY 2016 wage index, we identified and excluded 93 providers with aberrant data that should not be included in the proposed wage index. If data elements for *some* of these providers with aberrant data are corrected, we intend to include data from those providers in the final FY

2016 wage index'' (emphasis added). We note that we never anticipated that the data of all 93 hospitals would be corrected; we only anticipated that the data of *some* of those hospitals would be corrected. This is because approximately 50 hospitals were deleted from the FY 2016 proposed wage index for reasons that would make their data unresolvable, such as, but not limited to, termination (during or since the relevant past period), low/no Medicare utilization, being a CAH, or not reporting any wage data. Thus, ''aberrant'' hospitals are not limited to only hospitals that fail edits for reasonableness, but also include hospitals whose data are unresolvable. In fact, the number of hospitals deleted from the February or May 2015 PUFs due to having an extraordinarily high average hourly wage (and no other significant edit failures) was a small percentage of the 93 excluded hospitals (11.8 percent). Approximately 40 hospitals excluded from the February 2015 PUF had the potential to improve their data and be included in the May 2015 PUF and\or the final rule wage index. (In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49964), we stated that ''For the proposed FY 2015 wage index, we stated that we identified and excluded 50 providers with aberrant data that should not be included in the wage index, although we stated that if data elements are corrected, we intended to include data from those providers in the final FY 2015 wage index (79 FR 28064). We have since determined that we had only removed 49, not 50, providers with aberrant data from the proposed wage index.'' In an effort to avoid a similar miscounting of deleted hospitals for the FY 2016 proposed rule, we specified the total universe of deleted hospitals (93)—not just the number of hospitals with aberrant data which we anticipated would be able to be corrected as we had done for FY 2015. Essentially, the group of approximately 40 hospitals that were excluded during the development of the FY 2016 wage index and had the potential to improve their data is analogous to the 49 hospitals that were excluded from the FY 2015 proposed rule). As we stated earlier, we received corrected data or improved documentation for 34 hospitals. Therefore, we are including these 34 hospitals in the final FY 2016 wage index. Furthermore, of those hospitals with high average hourly wages that did object to their exclusion from the proposed wage index by submitting an April appeal or a public comment letter, we have determined that only 5 hospitals would remain out of the final FY 2016 wage index. This demonstrates the effectiveness of our process—hospitals were included in final wage index because these hospitals were responsive to the MACs' and CMS' requests for sufficient documentation to improve their data. Consequently, the vast majority of hospitals whose data were excluded from the proposed wage index but had the potential to improve their data are included in the FY 2016 final wage index. We believe the final wage index is all the more accurate as a result.

Regarding the particular hospital in CBSA 46140 to which one commenter referred, while the hospital's wage data were properly documented, the hospital does not merely have the highest average hourly wage in the CBSA; its average hourly wage is extremely and unusually high, significantly higher than the next highest average hourly wage in that CBSA and in the surrounding areas. We do not believe that the average hourly wage of this particular hospital accurately reflects the economic conditions in its labor market area during the FY 2012 cost reporting period. Therefore, its inclusion in the wage index would *not* ensure that the FY 2016 wage index represents the labor market area's current wages as compared to the national average of wages. Rather, its inclusion would distort the average hourly wage of its labor market area. Accordingly, we have exercised our discretion to remove this hospital's wage data from the FY 2016 wage index.

Furthermore, just as CMS has excluded certain hospitals from the wage index with extraordinarily high average hourly wages relative to their labor market areas, CMS also has excluded hospitals with extraordinarily low average hourly wages relative to their labor market areas. An objective comparison of the hospitals included in the FY 2016 preliminary PUF to the hospitals included in the February and May 2015 PUFs demonstrates CMS' ''fairness'' in evaluating the appropriateness and relativity of the wage data of hospitals with both extraordinarily low and extraordinarily high average hourly wages. While 5 hospitals with high extraordinarily high average hourly wages remain excluded from the FY 2016 final wage index, 14 hospitals with extraordinarily low average hourly wages also remain excluded from the FY 2016 final wage index. Therefore, we disagree with commenters' assertions that we have been ''arbitrary and capricious'' and have ''abused'' our discretion in excluding hospitals from the wage index.

Regarding the commenters' requests for notification of exclusion from the PUFs, such a notification process already exists. Each time a PUF is posted, CMS instructs the MACs to send letters to each of their hospitals notifying and instructing them to review their wage index data that were just posted. Hospitals that review each PUF and observe that they are excluded may then submit an April appeal to CMS, and/or contact CMS and the MAC to discuss possible ways to revise or verify their data for inclusion in the wage index. We believe the established annual wage index timetable grants sufficient time for hospitals to review, appeal, and/or correct their data. We also welcome State hospital associations to be more proactive in the process of urging their constituents to be responsive to the MACs' and CMS' requests for documentation and to become more involved in resolving issues related to aberrant data. We acknowledge the commenters' suggestions for increased transparency, disclosure of criteria for hospitals' exclusion, and improving awareness both at the State hospital association level and the hospital level. We note that it has never been CMS' policy to disclose audit protocol. However, in the future, we may consider a limited proposal regarding criteria for excluding a hospital's data from the wage index due to its overall average hourly wage being either too high or too low, as well as utilizing additional methods of communicating with stakeholders regarding the adequacy of their wage data.

D. Method for Computing the FY 2016 Unadjusted Wage Index

The method used to compute the FY 2016 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012, FY 2013, FY 2014, and FY 2015 final wage indexes without an occupational mix adjustment (76 FR 51591 through 51593, 77 FR 53366 through 53367, 78 FR 50587 through 50588, and 79 FR 49967, respectively).

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, 2011,

through April 15, 2013, 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 as we discussed in the proposed rule (80 FR 24464 through 24465), we are not making any changes to the usage for the FY 2016 wage index in this final rule. 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
10/14/2011	11/15/2011	1.02167
11/14/2011	12/15/2011	1.02029
12/14/2011	01/15/2012	1.01893
01/14/2012	02/15/2012	1.01756
02/14/2012	03/15/2012	1.01620
03/14/2012	04/15/2012	1.01484
04/14/2012	05/15/2012	1.01348
05/14/2012	06/15/2012	1.01213
06/14/2012	07/15/2012	1.01080
07/14/2012	08/15/2012	1.00951
08/14/2012	09/15/2012	1.00825
09/14/2012	10/15/2012	1.00699
10/14/2012	11/15/2012	1.00568
11/14/2012	12/15/2012	1.00433
12/14/2012	01/15/2013	1.00292
01/14/2013	02/15/2013	1.00148
02/14/2013	03/15/2013	1.00000
03/14/2013	04/15/2013	0.98259

For example, the midpoint of a cost reporting period beginning January 1, 2012, and ending December 31, 2012, is June 30, 2012. An adjustment factor of 1.01080 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as described above, the FY 2016 national average hourly wage (unadjusted for occupational mix) is $40.2911. The FY 2016 Puerto Rico overall average hourly wage (unadjusted for occupational mix) is $16.9153.

E. Occupational Mix Adjustment to the FY 2016 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. Development of Data for the FY 2016 Occupational Mix Adjustment Based on the 2013 Medicare Wage Index Occupational Mix Survey

As provided for under section 1886(d)(3)(E) of the Act, we collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49967 through 49968), the occupational mix adjustment to the FY 2015 wage index was based on data collected on the 2010 Occupational Mix Survey Hospital Reporting Form (CMS–10079 (2010)). For the FY 2016 wage index, we proposed to use the occupational mix data collected on the most recent 2013 occupational mix survey to compute the occupational mix adjustment for FY 2016, as discussed in section II.B.2. of the preamble of this final rule.

We did not receive any public comments on this proposal. Therefore, we are finalizing our policy to use the occupational mix data collected on the 2013 survey to compute the occupational mix adjustment for FY 2016. We are including data for 3,135 hospitals that also have wage data included in the FY 2016 wage index.

2. Use of 2013 Occupational Mix Survey for the FY 2016 Wage Index

Section 304(c) of Public Law 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 2010 to compute the occupational mix adjustment for the FY 2013, FY 2014, and FY 2015 wage index. Therefore, we were required to collect data in 2013 and are using these data to compute the occupational mix adjustment for the FY 2016 wage index. We also plan to use the 2013 survey data for the FY 2017 and FY 2018 wage indexes. A new measurement of occupational mix will be required for FY 2019.

On December 7, 2012, we published in the **Federal Register** a notice soliciting comments on the proposed 2013 Medicare Wage Index Occupational Mix Survey (77 FR 73032 through 73033). The new 2013 survey (which we note was used for the proposed FY 2016 wage index) includes the same data elements and definitions as the 2010 survey and provides for the collection of hospital-specific wages and hours data for nursing employees for calendar year 2013 (that is, payroll periods ending between January 1, 2013 and December 31, 2013). The comment period for the notice ended on February 5, 2013. After considering the public comments that we received on the December 2012 notice, we made a few minor editorial changes and published the 2013 survey in the **Federal Register** on February 28, 2013 (78 FR 13679 through 13680). This survey was approved by OMB on May 14, 2013, and is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/wage-index-occupational-mix-survey2013.pdf*.

The 2013 Occupational Mix Survey Hospital Reporting Form CMS–10079 for the Wage Index Beginning FY 2016 (in Excel format) is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html*. Hospitals were required to submit their completed 2013 surveys to their MACs by July 1, 2014. The preliminary, unaudited 2013 survey data were posted on the CMS Web site on July 11, 2014.

As with the Worksheet S–3, Parts II and III cost report wage data, we asked our MACs to revise or verify data elements in hospitals' occupational mix surveys that result in certain edit failures. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24465), we stated that certain surveys with aberrant data elements were excluded from the proposed FY 2016 wage index, but any data elements resolved and revised in time to be included in the final wage index would be reflected in the FY 2016 IPPS/LTCH PPS final rule.

3. Calculation of the Occupational Mix Adjustment for FY 2016

For FY 2016, we proposed to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012, FY 2013, FY 2014, and FY 2015 wage indexes (76 FR 51582 through 51586, 77 FR 53367 through 53368, 78 FR 50588 through 50589, and 79 FR 49968, respectively). 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 2016 wage index. For the FY 2016 wage index, because we are using the Worksheet S–3, Parts II and III wage data of 3,362 hospitals, and we are using the occupational mix surveys of 3,135 hospitals for which we also have Worksheet S–3 wage data, that represents a ''response'' rate of 93.2 percent (3,135/3,362). In the FY 2016 wage index established in this final rule, we applied 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).

In the FY 2011 IPPS/LTCH PPS proposed rule and final rule (75 FR 23943 and 75 FR 50167, respectively), we stated that, in order to gain a better understanding of why some hospitals are not submitting the occupational mix data, we will require hospitals that do not submit occupational mix data to provide an explanation for not complying. This requirement was effective for the 2013 occupational mix survey as well as the 2010 occupational mix survey. We instructed MACs to continue gathering this information as part of the FY 2016 wage index desk review process. We stated that we would review these data for future analysis and consideration of potential penalties for noncompliant hospitals.

Comment: One commenter stated that all hospitals should be obligated to submit the occupational mix survey because failure to complete the survey jeopardizes the accuracy of the wage index. The commenter added that a penalty should be instituted for nonsubmitters. The same commenter also requested that, pending CMS' analysis of the Commuting Based Wage Index and given the Institute of Medicine's study on geographic variation in hospital wage costs, CMS eliminate the occupational mix survey and the significant reporting burden it creates.

Response: We appreciate the commenter's concern for the accuracy of the wage index. We have continually requested that all hospitals complete and submit the occupational mix surveys. We did not propose a particular penalty for hospitals that did not submit the 2013 occupational mix survey, but we are continuing to consider for future rulemaking various options for ensuring full compliance. Regarding the commenter's request that CMS eliminate the survey due to the burden it creates, section 1886(d)(3)(E) of the Act requires us to measure the earnings and paid hours of employment by occupational category. As long as this statutory requirement remains in place, there may be some amount of administrative burden involved in reporting these data.

After consideration of public comments we received, we are calculating the occupational mix adjustment factor using the same methodology that we used for the FY 2012, FY 2013, FY 2014, and FY 2015 wage indexes. As a result of applying this methodology, the FY 2016 occupational mix adjusted national average hourly wage is $40.2555. The FY 2016 occupational mix adjusted Puerto Rico-specific average hourly wage is $16.8711.

F. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2016 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this final rule, for FY 2016, we apply the occupational mix adjustment to 100 percent of the FY 2016 wage index. We calculated the occupational mix adjustment using data from the 2013 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 2016 wage index results in a national average hourly wage of $40.2555 and a Puerto-Rico specific average hourly wage of $16.8711. After excluding data of hospitals that either submitted aberrant data that failed critical edits or that did not have FY 2012 Worksheet S–3, Parts II and III, cost report data for use in calculating the FY 2016 wage index, we calculated the FY 2016 wage index using the occupational mix survey data from 3,135 hospitals. For the FY 2016 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,362 hospitals, and we are using the occupational mix survey data of 3,135 hospitals for which we also have Worksheet S–3 wage data. The FY 2016 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	38.823902202
National LPN and Surgical Technician	22.767361175
National Nurse Aide, Orderly, and Attendant	15.955866208
National Medical Assistant	18.006207097
National Nurse Category	32.875956041

The national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $32.875956041. Hospitals with a nurse category average hourly wage (as calculated in Step 4 of the occupational mix calculation) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6 of the occupational mix calculation) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4 of the occupational mix calculation) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6 of the occupational mix calculation) of greater than 1.0.

Based on the 2013 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 42.62 percent, and the national percentage of hospital employees in the all other occupations category is 57.38 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 25.65 percent in one CBSA to a high of 73.52 percent in another CBSA.

The FY 2016 Puerto Rico-specific 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	Puerto Rico average hourly wage
Puerto Rico RN	16.686558980
Puerto Rico LPN and Surgical Technician	10.308310116
Puerto Rico Nurse Aide, Orderly, and Attendant	9.695410146
Puerto Rico Medical Assistant	21.962356196
Puerto Rico Nurse Category	14.491916770

Based on the 2013 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the Puerto Rico percentage of hospital employees in the nurse category is 50.97 percent, and the Puerto Rico percentage of hospital employees in the all other occupations category is 49.03 percent.

We also compared the FY 2016 wage data adjusted for occupational mix from the 2013 survey to the FY 2016 wage data adjusted for occupational mix from the 2010 survey. This analysis illustrates the effect on area wage indexes of using the 2013 survey data compared to the 2010 survey data; that is, it shows whether hospitals' wage indexes will increase or decrease under the 2013 survey data as compared to the prior 2010 survey data. Of the 407 urban CBSAs and 47 rural CBSAs, our analysis shows that the FY 2016 wage index values for 185 (45.5 percent) urban areas and 19 (40.4 percent) rural areas will increase. Forty-eight (11.8 percent) urban areas will increase by greater than or equal to 1 percent but less than 5 percent, and 5 (1.2 percent) urban areas will increase by 5 percent or more. Five (10.6 percent) rural areas will increase by greater than or equal to 1 percent but less than 5 percent, and no rural areas will increase by 5 percent or more. However, the wage index values for 218 (53.6 percent) urban areas and 27 (57.4 percent) rural areas will decrease using the 2013 survey data. Seventy-four (18.2 percent) urban areas will decrease by greater than or equal to 1 percent but less than 5 percent, and one (0.2 percent) urban area will decrease by 5 percent or more. Eight (17.0 percent) rural areas will decrease by greater than or equal to 1 percent but less than 5 percent, and no rural areas will decrease by 5 percent or more. The largest positive impacts using the 2013 survey data compared to the 2010 survey data are 15.1 percent for an urban area and 3.8 percent for a rural area. The largest negative impacts are 5.0 percent for an urban area and 1.95 percent for two rural areas. Four urban areas and one rural area will be unaffected. These results indicate that the wage indexes of more CBSAs overall (54.0 percent) will decrease due to application of the 2013 occupational mix survey data as compared to the 2010 occupational mix survey data to the wage index. Further, a larger percentage of urban areas (45.5 percent) will benefit from the use of the 2013 occupational mix survey data as compared to the 2010 occupational mix survey data than will rural areas (40.4 percent).

We compared the FY 2016 occupational mix adjusted wage indexes for each CBSA to the unadjusted wage indexes for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the wage index values for 219 (53.8 percent) urban areas and 24 (51.1 percent) rural areas will increase. One hundred three (25.3 percent) urban areas will increase by greater than or equal to 1 percent but less than 5 percent, and 6 (1.5 percent) urban areas will increase by 5 percent or more. Nine (19.1 percent) rural areas will increase by greater than or equal to 1 percent but less than 5 percent, and no rural areas will increase by 5 percent or more. However, the wage index values for 187 (45.9 percent) urban areas and 23 (48.9 percent) rural areas will decrease. Ninety-one (22.4 percent) urban areas will decrease by greater than or equal to 1percent but less than 5 percent, and no urban areas will decrease by 5 percent or more. Seven (14.9 percent) rural areas will decrease by greater than or equal to 1 percent but less than 5 percent, and no rural areas will decrease by 5 percent or more. The largest positive impacts will be 17.4 percent for an urban area and 2.7 percent for one rural area. The largest negative impacts will be 4.7 percent for an urban area and 2.1 percent for a rural area. One urban area will remain unchanged by application of the occupational mix adjustment, and no rural areas will remain unchanged by application of the occupational mix adjustment. These results indicate that a larger percentage of urban areas (53.8 percent) will benefit from application of the occupational mix adjustment than will rural areas (51.1 percent).

G. Transitional Wage Indexes

1. Background

As we stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24467 through 24469), in the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28060 and 49957, respectively), we stated that, overall, we believed implementing the new OMB labor market area delineations would result in wage index values being more representative of the actual costs of labor in a given area. However, we recognized that some hospitals would experience decreases in wage index values as a result of the implementation of these new OMB labor market area delineations. We also realized that some hospitals would have higher wage index values due to the implementation of the new OMB labor market area delineations.

The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957) explained the methodology utilized in implementing prior transition periods when adopting changes that have significant payment implications, particularly large negative impacts. Specifically, for FY 2005, in the FY 2005 IPPS final rule (69 FR 49032 through 49034), we provided transitional wage indexes when the OMB definitions were implemented after the 2000 Census. The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49962) established similar transition methodologies to mitigate any negative payment impacts experienced by hospitals due to our adoption of the new OMB labor market area delineations for FY 2015.

As finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49960) and as discussed below, for FY 2016, we are in the second year of two 3-year transition periods for wage index: One for hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act); and one for hospitals deemed urban under section 1886(d)(8)(B) of the Act where the urban area became rural under the new OMB delineations. In addition, the 1-year transition that we applied in FY 2015 for hospitals that experienced a decrease

in wage index under the new OMB delineations expires at the end of FY 2015 and does not apply in FY 2016.

2. Transition for Hospitals in Urban Areas That Became Rural

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49959), for hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act), we adopted a policy to assign them the urban wage index value of the CBSA in which they are physically located for FY 2014 for a period of 3 fiscal years (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index). FY 2016 will represent the second year of this transition policy, and we did not propose any changes to this policy in the FY 2016 IPPS/LTCH PPS proposed rule. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957), we stated our belief that it is appropriate to apply a 3-year transition period for hospitals located in urban counties that would become rural under the new OMB delineations, given the potentially significant payment impacts for these hospitals. We continue to believe that assigning the wage index of the hospitals' FY 2014 area for a 3-year transition is the simplest and most effective method for mitigating negative payment impacts due to the adoption of the new OMB delineations.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR49959), we noted that there were situations where a hospital could not be assigned the wage index value of the CBSA in which it geographically was located in FY 2014 because that CBSA split and no longer exists and some or all of the constituent counties were added to another urban labor market area under the new OMB delineations. If the hospital could not be assigned the wage index value of the CBSA in which it was geographically located in FY 2014 because that CBSA split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, we established that hospitals located in such counties that became rural under the new OMB delineations were assigned the wage index of the urban labor market area that contains the urban county in their FY 2014 CBSA to which they are closest (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). Any such assignment made in FY 2015 will continue for FYs 2016 and 2017, except as discussed below. We continue to believe this approach minimizes the negative effects of the change in the OMB delineations.

Under the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, if a hospital for FY 2014 was located in an urban county that became rural for FY 2015 under the new OMB delineations and such hospital sought and was granted reclassification or redesignation for FY 2015 or such hospital seeks and is granted any reclassification or redesignation for FY 2016 or FY 2017, the hospital will permanently lose its 3-year transitional assigned wage index status, and will not be eligible to reinstate it. We established the transition policy to assist hospitals if they experience a negative payment impact specifically due to the adoption of the new OMB delineations in FY 2015. If a hospital chooses to forego this transition adjustment by obtaining some form of reclassification or redesignation, we do not believe reinstatement of this transition adjustment would be appropriate. The purpose of the transition adjustment policy is to assist hospitals that may be negatively impacted by the new OMB delineations in transitioning to a wage index based on these delineations. By obtaining a reclassification or redesignation, we believe that the hospital has made the determination that the transition adjustment is not necessary because it has other viable options for mitigating the impact of the transition to the new OMB delineations.

As we did for FY 2015 (79 FR 49959), and as stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24468), with respect to the wage index computation for FY 2016, we are following our existing policy regarding the inclusion of a hospital's wage index data in the CBSA in which it is geographically located (we refer readers to Step 6 of the method for computing the unadjusted wage index in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592)). Accordingly, as we began with FY 2015, for FY 2016, the wage data of all hospitals receiving this type of 3-year transition adjustment were included in the statewide rural area in which they are geographically located under the new OMB labor market area delineations. After the 3-year transition period, beginning in FY 2018, these formerly urban hospitals discussed above will receive their statewide rural wage index, absent any reclassification or redesignation.

In addition, we established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959) that the hospitals receiving this 3-year transition because they are in counties that were urban under the FY 2014 CBSA definitions, but are rural under the new OMB delineations, will not be considered urban hospitals. Rather, they will maintain their status as rural hospitals for other payment considerations. This is because our application of a 3-year transitional wage index for these newly rural hospitals only applies for the purpose of calculating the wage index under our adoption of the new OMB delineations.

We did not receive any public comments on these provisions in the proposed rule.

3. Transition for Hospitals Deemed Urban Under Section 1886(d)(8)(B) of the Act Where the Urban Area Became Rural Under the New OMB Delineations

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24468), and as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959 through 49960), there were some hospitals that, for FY 2014, were geographically located in rural areas but were deemed to be urban under section 1886(d)(8)(B) of the Act. For FY 2015, some of these hospitals redesignated under section 1886(d)(8)(B) of the Act were no longer eligible for deemed urban status under the new OMB delineations, as discussed in detail in section III.H.3. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Similar to the policy implemented in the FY 2005 IPPS final rule (69 FR 49059), and consistent with the FY 2015 policy we established for other hospitals in counties that were urban and became rural under the new OMB delineations, we finalized a policy to apply a 3-year transition to these hospitals redesignated to urban areas under section 1886(d)(8)(B) of the Act for FY 2014 that are no longer deemed urban under the new OMB delineations and revert to being rural.

For FY 2016, we did not propose any changes to this policy and are continuing to the second year of the implementation of our policy to provide a 3-year transition adjustment to hospitals that are deemed urban under section 1886(d)(8)(B) of the Act under the FY 2014 labor market area delineations, but are considered rural under the new OMB delineations, assuming no other form of wage index reclassification or redesignation is granted. We assign these hospitals the area wage index value of hospitals reclassified to the urban CBSA (that is,

the attaching wage index) to which they were redesignated in FY 2014 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). If the hospital cannot be assigned the reclassified wage index value of the CBSA to which it was redesignated in FY 2014 because that CBSA was split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, such hospitals are assigned the wage index of the hospitals reclassified to the urban labor market area that contains the urban county in their FY 2014 redesignated CBSA to which they are closest. We assign these hospitals the area wage index of hospitals reclassified to a CBSA because hospitals deemed urban under section 1886(d)(8)(B) of the Act are treated as reclassified under current policy, under which such hospitals receive an area wage index that includes wage data of all hospitals reclassified to the area. This wage index assignment will be forfeited if the hospital obtains any form of wage index reclassification or redesignation.

We did not receive any public comments specific to either of the 3-year transition policies for hospitals that were located in an urban county that became rural under the new OMB delineations or for hospitals deemed urban under section 1886(d)(8)(B) of the Act where the urban area became rural under the new OMB delineations. Fiscal year 2016 will be the second year of the 3-year transition period. We also remind hospitals that if any affected hospital is approved for any wage index reclassification or redesignation in FY 2016 or FY 2017, it will no longer be eligible for the remaining years of the transitional wage index.

4. Expiring Transition for Hospitals That Experience a Decrease in Wage Index Under the New OMB Delineations

As we indicated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24468), in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49960 through 49962), we stated that, while we believe that instituting the latest OMB labor market area delineations would create a more accurate wage index system, we also recognized that implementing the latest OMB delineations may cause some short-term instability in hospital payments. Therefore, in addition to the 3-year transition adjustments for hospitals being transitioned from urban to rural status as discussed earlier, in the FY 2015 IPPS/LTCH PPS final rule, we established a 1-year blended wage index for all hospitals that would experience any decrease in their actual payment wage index. This 1-year blended wage index expires at the end of FY 2015. We did not propose any additional transition adjustment for hospitals that experienced a decrease in wage index values due to the adoption of the new OMB delineations for FY 2015 and, as discussed previously, will continue the 3-year transition adjustments for hospitals that changed from urban to rural status that we finalized in the FY 2015 IPPS/LTCH PPS final rule. We established a longer 3-year transition adjustment for hospitals losing urban status because there are significantly fewer affected urban-to-rural hospitals, and we believe the negative impacts to a hospital shifting from urban to rural status are typically greater than other types of transitions. We stated our belief that a transition period longer than 1 year to address other impacts of the adoption of the new OMB delineations would reduce the accuracy of the overall labor market area wage index system because far more hospitals would be affected. As we stated in FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24468), the 1-year transition for all negatively affected hospitals in FY 2015 provided an opportunity for hospitals to evaluate potential reclassification options and mitigated initial negative impacts due to labor market assignment changes. We continue to believe that the adoption of the latest labor market delineations improve the accuracy and integrity of the hospital wage index system. Therefore, we believe it is necessary to allow this transition to expire.

Comment: The majority of commenters expressed appreciation to CMS for providing a transitional wage index to mitigate negative effects due to the application of the new OMB labor market delineations. They also supported CMS' plan to discontinue the 1-year transition in FY 2016. One commenter requested that the transition period be extended for at least one additional fiscal year, with a suggested ''75/25 percent'' methodology to provide some support for hospitals that will continue to be negatively affected by the new OMB delineations.

Response: We appreciate the commenters' support of the transition policies. We continue to believe that the 1-year transition for all negatively affected hospitals in FY 2015 provided an ample opportunity for hospitals to evaluate potential reclassification options, and mitigated initial negative impacts due to labor market assignment changes. Therefore, we do not believe that an extension of the transition period is warranted. We continue to believe that the adoption of the latest labor market delineations improves the accuracy and integrity of the hospital wage index system.

Thus, we are allowing the transition adjustment to expire at the end of FY 2015.

5. Budget Neutrality

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), for FY 2015, we applied the 3-year transition and 50/50 blended wage index adjustments in a budget neutral manner. For FY 2016, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24469), we proposed to apply the 3-year transition adjustments in a budget neutral manner. We proposed to make an adjustment to the standardized amount to ensure that the total payments, including the effect of the transition provisions, would equal what payments would have been if we were not providing for any transitional wage indexes under the new OMB delineations. For a complete discussion on the budget neutrality adjustment for FY 2016, we refer readers to section II.A.4.b. of the Addendum to this final rule, where we also address any public comments we received.

In this final rule, for FY 2016, we are applying the 3-year transition adjustments in a budget neutral manner. We are making an adjustment to the standardized amount to ensure that the total payments, including the effect of the transition provisions, will equal what payments would have been if we were not providing for any transitional wage indexes under the new OMB delineations.

H. Application of the Rural, Imputed, and Frontier Floors

1. Rural Floor

Section 4410(a) of Pubic 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 final FY 2016 wage index associated with this final rule and available via the Internet on the CMS Web site, we estimated that 346 hospitals will receive an increase in their FY 2016 wage index due to the application of the rural floor.

Comment: Commenters thanked CMS for providing a State-specific analysis of

the effects of nationwide budget neutrality of the rural floor required under section 3141 of the Affordable Care Act and requested additional long-term analysis of payment distortions produced by nationwide rural floor budget neutrality.

Response: We appreciate the commenters' continued concern regarding rural floor budget neutrality. We are publishing State-specific rural floor impacts in Appendix A of this final rule and will consider additional analysis in future rulemaking.

2. Imputed Floor for FY 2016

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 five times, the last of which was adopted in the FY 2015 IPPS/LTCH PPS final rule and is set to expire on September 30, 2015. (We refer readers to further discussions of the imputed floor in the FY 2014 and FY 2015 IPPS/LTCH PPS final rules (78 FR 50589 through 50590 and 79 FR 49969 through 49970, 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.J. of the preamble of this final 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 2 (formerly Table 4D) associated with the FY 2013 IPPS/LTCH PPS final rule, which is available via the Internet on the CMS Web site, 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 new 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 these final rules, we also revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the 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.

For FY 2016, we proposed to extend the imputed floor policy (both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2016, while we continue to explore potential wage index reforms (80 FR 24469 through 24470). We proposed to revise the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this proposed additional 1-year extension. We invited public comments on the proposed additional 1-year extension of the imputed floor through September 30, 2016.

Comment: Several commenters supported the CMS proposal to extend the imputed floor for 1 year, stating that it establishes an approach to remedy the competitive disadvantage suffered by all-urban States due to several unique factors common to these areas. One commenter who supported the proposal recommended that CMS allow public input prior to finalizing any decisions regarding the imputed floor. Another commenter opposed the proposed 1-year extension, citing CMS' previous assessment in the FY 2008 proposed rule that this type of floor should apply only when required by statute.

Response: We appreciate the commenters' support for the proposal to extend the imputed floor for 1 year. As we have done every year since the

initial proposal of the imputed floor, we provide and will continue to provide the industry with the opportunity to provide input on our proposals prior to finalizing any decisions regarding the imputed floor policy. We understand the concerns of the commenter who opposed the proposal, and will give further consideration to all comments as we continue to explore potential wage index reforms. As we stated in the FY 2005 IPPS final rule (69 FR 49110), we note that the Secretary has broad authority under section 1886(d)(3)(E) of the Act to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wage and wage-related cost of the DRG prospective payment rates for area differences in hospital wage levels by a factor (established by the Secretary). Therefore, we believe that we do have the discretion to adopt a policy that would adjust wage indexes in the stated manner. We adopted the imputed floor policy and subsequently extended it through notice-and-comment rulemaking to address concerns from hospitals in all-urban States.

After consideration of the public comments we received, we are finalizing our proposal without modification to extend the imputed floor policy under both the original methodology and the alternative methodology for an additional year, through September 30, 2016. We also are adopting as final the proposed revisions to § 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor.

The wage index and impact tables associated with this FY 2016 IPPS/LTCH PPS final rule (which are available via the Internet on the CMS Web site) reflect the continued application of the imputed floor policy at § 412.64(h)(4) and a national budget neutrality adjustment for the imputed floor for FY 2016. There are 21 hospitals in New Jersey that will receive an increase in their FY 2016 wage index due to the continued application of the imputed floor policy under the original methodology and 4 hospitals in Rhode Island that will benefit under the alternative methodology. No hospitals in Delaware will benefit from the imputed floor under either methodology because all hospitals in the affected labor market areas will receive a higher wage index value due to reclassification.

3. State Frontier Floor

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 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)). Forty-eight hospitals will receive the frontier floor value of 1.0000 for their FY 2016 wage index in this final rule. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. Although Nevada also is defined as a frontier State, its FY 2016 rural floor value of 1.0194 is greater than 1.0000, and therefore, no Nevada hospitals will receive a frontier floor value for their FY 2016 wage index. We did not propose any changes to the frontier floor policy for FY 2016, and we did not receive any public comments on the issue.

The areas affected by the rural, imputed, and frontier floor policies for the FY 2016 wage index are identified in Table 2 (formerly Table 4D) associated with this final rule, which is available via the Internet on the CMS Web site.

I. FY 2016 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24470), we proposed to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. The wage index tables have consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that are made available via the Internet on the CMS Web site. However, with the exception of Table 4E, we proposed to streamline and consolidate these 11 tables into 2 tables. We refer readers to section VI. of the Addendum to this final rule for a discussion of the proposed and finalized revisions to the wage index tables.

J. 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 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 (generally 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/LTCH PPS 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 that we proposed for FY 2016 and are finalizing in this final rule, and the policies for the effects of hospitals' reclassifications and redesignations on the wage index, are the same as those 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.

Comment: A few commenters stated that, in cases where a countywide (group) reclassification had been previously approved by the MGCRB, a new hospital is not able to obtain the same reclassified wage index as the countywide group until the first year that individual hospital's wage index data match one of the 3 years' data used by the MGCRB and a new 3-year countywide reclassification is requested by the county's hospitals (which can be a 4-year delay). The commenters were concerned that such a new hospital will have a wage index lower than the hospitals with which it competes for skilled labor. The commenters suggested that CMS change its policy to allow for a timelier competitive wage index for new hospitals. The commenters believed that there is a significant disincentive for stable hospitals to acquire other nearby facilities that are in financial distress because the ''new'' hospital would not be immediately eligible to participate in reclassification.

Other commenters suggested that the proximity rule for countywide reclassifications for hospitals in an urban county be modified to permit adjacent county reclassifications, regardless of whether they are in the same CSA or CBSA, or at a minimum, create an exception that would allow this in the event that half of the hospitals in the county are seeking to reclassify.

Response: We thank the commenters for their comments. We already have established criteria and processes for MGCRB reclassification, which are specified in 42 CFR 412.230 et seq., and

we did not propose any changes to these provisions for FY 2016. Consequently, we are not making any changes to address the commenters' concerns at this time. We are making a clarification in policy relating to the example cited by some commenters regarding hospitals that acquire other providers located in different labor market areas with current reclassifications, which is addressed in a response to a related comment under section III.J.2.a. of the preamble of this final rule.

2. FY 2016 MGCRB Reclassifications

a. FY 2016 Reclassification Requirements and Approvals

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 specified in regulations under 42 CFR 412.230 through 412.280.

At the time this final rule was constructed, the MGCRB had completed its review of FY 2016 reclassification requests. Based on such reviews, there are 282 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2016 that did not withdraw or terminate their reclassifications within 45 days of the publication of the FY 2016 proposed rule. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2016, hospitals reclassified beginning in FY 2014 or FY 2015 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 248 hospitals approved for wage index reclassifications in FY 2014 that continue for FY 2016, and 311 hospitals approved for wage index reclassifications in FY 2015 that continue for FY 2016. Of all the hospitals approved for reclassification for FY 2014, FY 2015, and FY 2016, based upon the review at the time of this final rule, 841 hospitals are in a reclassification status for FY 2016. We note that the number of hospitals with active reclassifications changed between the proposed rule and the final rule because hospitals have the opportunity to withdraw or terminate their reclassification, or reinstate previously withdrawn reclassifications, within 45 days of the publication of the FY 2016 proposed rule.

Under the regulations at 42 CFR 412.273, hospitals are permitted to withdraw or terminate their MGCRB reclassification within 45 days of the publication of a proposed rule. 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 42 CFR 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).

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 2016 are incorporated into the wage index values published in this FY 2016 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.

Comment: One commenter stated that CMS' policy that hospitals must request to withdraw or terminate MGCRB reclassifications within 45 days of the proposed rule is problematic because a hospital could terminate a reclassification based on information in the proposed rule, and with the publication of the final rule, discover that its original reclassified status was more desirable. The commenter stated that hospitals cannot make informed decisions concerning their reclassification status based on values in a proposed rule that are likely to change and, therefore, recommended that CMS revise its existing policy to permit hospitals to withdraw or terminate their reclassification status within 45 days of the publication of the final rule.

Response: We did not make any proposals to change any of the reclassification processes or criteria for FY 2016. Any changes to the reclassification processes or criteria would need to be issued through notice-and-comment rulemaking. Consequently, we are not making any changes to address the commenter's concerns at this time. We maintain that information provided in the proposed rule constitutes the best available data to assist hospitals in making reclassification decisions. The values published in the final rule represent the final wage index values reflective of reclassification decisions.

Comment: One commenter requested clarification of the reclassification status in the case of a Connecticut hospital that acquired another hospital in a different labor market area. According to the commenter, the acquired hospital would become a subordinate remote location of the acquiring hospital (that is, a ''multicampus'' provider). The commenter stated that the acquired hospital had individual reclassification applications approved to begin in FY 2014, 2015, and 2016, and the hospital had requested termination of the FY 2016 reclassification and reinstatement of the hospital's FY 2015 reclassification.

Response: Our longstanding Medicare policy is to terminate reclassification status for a hospital whose CCN is no longer active because the MGCRB makes its reclassification decisions based on CCNs. We believe this policy results in more accurate reclassifications when compiling CBSA labor market wage data, as it is generally the case that hospitals that have terminated operations can no longer make timely and informed decisions regarding reclassification statuses, which could have ramifications for various wage index floors and labor market values. However, in this case, the acquiring hospital accepted the provider agreement of the acquired hospital located in a different market area, and the resulting merged hospital desires that the subordinate campus continue to receive previously approved reclassification benefits. While the original CCN for the acquired hospital would be considered ''tied out'' by CMS, we do believe that the acquiring hospital should be able to make determinations regarding the reclassification status of the subordinate campus located in a different labor market area if it accepted the provider agreement of that subordinate campus. Therefore, we are clarifying our wage index reclassification policy to address the specific situations where a hospital merges with or acquires another hospital located in a different labor market area, creating a ''multicampus'' hospital, and accepts the provider agreement of the acquired hospital. If the acquired campus (that is, the hospital whose CCN will no longer be active) has remaining years left on a MGCRB reclassification, this reclassification status remains in effect for the subordinate campus located in a different market area. This clarification only applies to circumstances where the Medicare provider agreement is

accepted by the acquiring hospital located in a different market area. We also wish to clarify that the acquiring hospital is authorized to make timely requests to terminate, withdraw, or reinstate any reclassification for the subordinate campus for any remaining years of the reclassification. We believe this policy results in more accurate labor market wage index values, and is consistent with current regulations regarding reclassification status of ''multicampus'' hospitals at § 412.230(d)(2)(v). Therefore, in response to the commenter, the hospital is eligible to terminate the reclassification approved to begin in FY 2016 and to reinstate a previously existing reclassification. CMS will make the appropriate adjustments to the payment systems to ensure the subordinate campus of the acquiring hospital is paid under the correct reclassification status.

b. Applications for Reclassifications for FY 2017

Applications for FY 2017 reclassifications are due to the MGCRB by September 1, 2015 (the first working day of September 2015). 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 via the Internet on the CMS Web site at: *http://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: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

3. Redesignation of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B)(i) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute if certain adjacency and commuting criteria are met. The criteria utilize standards for designating Metropolitan Statistical Areas published in the **Federal Register** by the Director of the Office of Management and Budget (OMB) based on the most recently available decennial population data. Effective beginning FY 2015, we used the new OMB delineations based on the 2010 Decennial Census data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. Hospitals located in these counties are referred to as ''Lugar'' hospitals and the counties themselves are often referred to as ''Lugar'' counties. The chart for this FY 2016 IPPS/LTCH PPS final rule which includes the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act is available via the Internet on the CMS Web site.

We did not receive any public comments on this listing that accompanied the FY 2016 IPPS/LTCH PPS proposed rule.

4. Waiving Lugar Redesignation for the Out-Migration Adjustment

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, including being considered rural for the DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.D. of the preamble of this final rule.)

In addition, we adopted a minor procedural change in that rule that allows 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. Therefore, under the procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless, prior to its second or third year of eligibility, the hospital explicitly notifies CMS in writing, within the required period (generally 45 days from the publication of the proposed rule), that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment. If the hospital does notify CMS that it is electing to return to its deemed urban status, it would again be treated as urban for all IPPS payment purposes.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) for a detailed discussion of the policy and process for waiving Lugar status for the out-migration adjustment.

We did not receive any public comments on the discussion of this policy in the FY 2016 IPPS/LTCH PPS proposed rule.

K. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

1. Background

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.

2. New Data Source for the FY 2016 Out-Migration Adjustment

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 which was 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 the 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 using the 2010 Census data beginning with FY 2016. We reviewed and analyzed the alternative dataset from the Census Bureau and proposed new out-migration adjustments in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24471

through 24472), as discussed below (as we indicated we would in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49984 through 49985).

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24471), to determine the new out-migration adjustments and applicable counties that we proposed 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. The tabulation was specific to hospital military and civilian employees (hospital sector Census code 8190/NAICS code 622) who worked in the 50 States, Washington, DC, and Puerto Rico and, therefore, provided information about commuting patterns of workers at the county level for residents of the 50 States, Washington, DC, and Puerto Rico. For the ACS, the Census Bureau selects a random sample of addresses where workers reside to be included in the survey, and the sample is designed to ensure good geographic coverage. The ACS samples approximately 3.54 million resident addresses per year. The results of the ACS are used to formulate descriptive population estimates, and, as such, the sample on which the dataset is based represents the actual figures that would be obtained from a complete count.

We did not receive any public comments on the new data source for the FY 2016 out-migration adjustment discussed in the FY 2016 IPPS/LTCH PPS proposed rule.

3. FY 2016 Out-Migration Adjustment

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 for the out-migration adjustment. For FY 2016 and subsequent years, until such time that CMS finalizes out-migration adjustments based on the next Census, we proposed that the out-migration adjustment be based on the data derived from the custom tabulation of the ACS described in section III.K.2. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24471 and 24472) and this final rule. As discussed above, we believe that these data are the most appropriate to establish qualifying counties because they are the most accurate and up-to-date data that are available to us. We proposed that the FY 2016 out-migration adjustments continue to be based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment. We have applied these same policies, procedures, and computations since FY 2012 and we believe they continue to be appropriate for FY 2016. (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 (formerly Table 4J) associated with this final rule (which is available via the Internet on the CMS Web site) lists the final out-migration adjustments for the FY 2016 wage index.

Comment: Several commenters supported the CMS proposed wage index updates for the out-migration adjustment for FY 2016.

Response: We appreciate the commenters' support.

Therefore, we are finalizing the FY 2016 update to the out-migration data as proposed. The FY 2016 out-migration adjustment is based on the data derived from the custom tabulation of the ACS. The FY 2016 out-migration adjustments continue to be based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment.

4. Use of Out-Migration Adjustment Data Applied for FY 2014 or FY 2015 for 3 Years

Section 1886(d)(13)(F) of the Act states that a wage index increase under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to waive the application of such wage index increase. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49984 through 49985), we stated that even if we proposed to adopt new out-migration adjustment data for FY 2016, hospitals that are already receiving an out-migration adjustment beginning with a fiscal year prior to FY 2016 would still receive their out-migration adjustment based on the data used prior to FY 2016 for the years that remain of their 3-year qualification period in FY 2016 and after. Therefore, for FY 2016, hospitals that qualified in FY 2014 or FY 2015 to receive the out-migration adjustment based on the commuting data and the CBSA delineations used for FY 2014 will continue to receive the same out-migration adjustment for the remainder of their 3-year qualification period. For example, if a hospital qualified for the out-migration adjustment in FY 2014, but also will qualify in FY 2016 under the new commuting patterns and the new OMB labor market area delineations for FY 2016, this hospital will still receive the out-migration adjustment based on the commuting data and the CBSA delineations used for FY 2014, regardless of whether the FY 2016 adjustment is higher or lower than the adjustment based on FY 2014 data. If the hospital qualifies in FY 2017 (after the expiration of the 3-year qualifying period for the out-migration adjustment, which began in FY 2014) to receive the out-migration adjustment based on the new commuting data and OMB delineations in effect in FY 2017, it could receive the out-migration adjustment based on the new data for FYs 2017, 2018, and 2019. Conversely, for example, if a hospital qualified for the out-migration adjustment in FY 2014, but would *not* qualify in FY 2016 under the new commuting patterns and the new OMB delineations for FY 2016, this hospital will still receive the out-migration adjustment based on the commuting data and the CBSA delineations used for FY 2014.

Based on the new out-migration adjustment data used for this FY 2016 IPPS/LTCH final rule, 336 hospitals will receive the out-migration adjustment for FY 2016. Of hospitals that were eligible for the out-migration adjustment for FY 2015 but whose 3-year qualifying period for the out-migration adjustment expired, 6 hospitals are no longer eligible for the out-migration adjustment under the new data (3 hospitals in Alabama, 1 hospital in Missouri, and 2 hospital in Tennessee). Of the 336 hospitals, the out-migration adjustment of 248 hospitals will be unaffected, as these hospitals will receive the same out-migration adjustment because they are still within an existing 3-year eligibility period under the previous out-migration adjustment data. Of the 336 hospitals, 12 hospitals would have received a higher out-migration adjustment using the new data (1 hospital in Alabama; 2 hospitals in Massachusetts; 1 hospital in Michigan; 4 hospitals in Pennsylvania; 2 hospitals in Tennessee; and 2 hospitals in Wisconsin) and 4 hospitals would have received a lower out-migration adjustment using the new data (1 hospital in Idaho, 2 hospitals in Oregon, and 1 hospital in South Carolina). Seventy-five hospitals are newly eligible for the out-migration adjustment in FY 2016 using the new data. The following table shows the States and Territory in

which the 75 affected hospitals are located:

State	Number of hospitals that are newly eligible under the new outmigration data for FY 2016
ALABAMA	2
ARKANSAS	3
CALIFORNIA	6
FLORIDA	4
GEORGIA	8
IDAHO	1
ILLINOIS	1
INDIANA	3
KANSAS	1
LOUISIANA	5
MAINE	1
MICHIGAN	2
MINNESOTA	1
MISSISSIPPI	3
MISSOURI	1
NORTH CAROLINA	4
OHIO	3
OKLAHOMA	2
PENNSYLVANIA	3
PUERTO RICO	5
SOUTH CAROLINA	1
TENNESSEE	3
TEXAS	6
VERMONT	1
WEST VIRGINIA	4
WISCONSIN	1
Total	75

L. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2016 wage index were made available on May 23, 2014, and the preliminary CY 2013 occupational mix data files on July 11, 2014, through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2016-Wage-Index-Home-Page.html*.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional public use file on our Web site 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 7, 2014, we instructed all MACs to inform the IPPS hospitals they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed below). We also instructed the MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in the May 23, 2014 wage data files and July 11, 2014 occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its MAC by October 6, 2014. 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 April 7, 2014 memorandum referenced above.

The MACs notified the hospitals by mid-February 2015 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' early-October revision requests. The MACs also submitted the revised data to CMS by December 16, 2014. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 13, 2015. Hospitals had until March 2, 2015, to submit requests to the MACs for reconsideration of adjustments made by the MACs as a result of the desk review, and to correct errors due to CMS' or the MAC's mishandling of the wage index data. 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 April 8, 2015. The deadline for a hospital to request CMS intervention in cases where the hospital disagreed with the MAC's policy interpretations was April 15, 2015. We note that, as we did for the FY 2015 wage index, for the FY 2016 wage index, in accordance with the FY 2016 wage index timeline posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2016-WI-Time-Table-Final.pdf*, the April appeals had to be sent via mail and email. We refer readers to the wage index timeline for complete details.

Hospitals were given the opportunity to examine Table 2, which was listed in section VI. of the Addendum to the proposed rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2016-Wage-Index-Home-Page.html*. Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2012 data used to construct the proposed FY 2016 wage index. We noted 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 February 27, 2015.

We posted the final wage index data public use files on May 1, 2015 on the Internet at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2016-Wage-Index-Home-Page.html*. The May 2015 public use files were 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 described above (revisions submitted to CMS by the MACs by April 8, 2015).

After the release of the May 2015 wage index data files, changes to the wage and occupational mix data could 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 April 8, 2015.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 13, 2015 wage index public use files.
- 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 May 2015 final public use files, a hospital believed 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 was given the opportunity to notify both its MAC and CMS regarding why the hospital believed an

error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital was required to send its request to CMS and to the MAC no later than June 1, 2015. Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2016 wage index timeline posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2016-WI-Time-Table-Final.pdf*, the June appeals were required to 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 by CMS and the MACs (that is, by June 1, 2015) were incorporated into the final wage index in this FY 2016 IPPS/LTCH PPS final rule, which will be effective October 1, 2015.

We created the processes described above to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2016 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above 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 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.

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data by May 1, 2015, they had 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 2016 wage index by August 2015, and the implementation of the FY 2016 wage index on October 1, 2015. 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 June 1, 2015, 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 June deadline for making corrections to the wage data for the following fiscal year's wage index (for example, June 1, 2015, for the FY 2016 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 Web site 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 June 1, 2015 deadline for the FY 2016 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 June 1, 2015 deadline for the FY 2016 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.

M. Labor-Related Share for the FY 2016 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 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we rebased and revised the hospital market basket. We established a FY 2010-based IPPS hospital market basket to replace the FY 2006-based IPPS hospital market basket, effective October 1, 2013. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2014. Using the FY 2010-based IPPS market basket, we finalized a labor-related share for FY 2014 and for FY 2015 of 69.6 percent. In addition, we implemented this revised and rebased labor-related share in a budget neutral manner. 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. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24474 through 24475), for FY 2016, we did not propose to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, employee benefits, contract labor, the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services. Therefore, for FY 2016, we proposed to continue to use a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2015.

Tables 1A and 1B, which were published in section VI. of the Addendum to the FY 2016 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site, reflected the proposed labor-related share. For FY 2016, for all IPPS hospitals whose wage indexes are less than or equal to 1.0000, we proposed to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indexes are greater than 1.000, for FY 2016, we proposed to apply the wage index to a proposed labor-related share of 69.6 percent of the national standardized amount. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24474 through 24475), we noted that, for Puerto Rico hospitals, the national labor-related share is 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0000.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50601 through 50603), we also rebased and revised the labor-related share for the Puerto Rico-specific standardized amounts using FY 2010 as a base year. We finalized a labor-related share for the Puerto Rico-specific standardized amounts for FY 2014 of 63.2 percent. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49990), for FY 2015, we did not make any further changes to the Puerto Rico-specific average proportion of operating costs that are attributable to wages and salaries, employee benefits, contract labor, the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services. For FY 2015, we continued to use a labor-related share for the Puerto Rico-specific standardized amounts of 63.2 percent for discharges occurring on or after October 1, 2014.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24475), for FY 2016, we proposed to continue to use a labor-related share for the Puerto Rico-specific standardized amounts of 63.2 percent for discharges occurring on or after October 1, 2015. Puerto Rico hospitals are paid based on 75 percent of the national standardized amounts and 25 percent of the Puerto Rico-specific standardized amounts. For FY 2016, we proposed that the labor-related share of a hospital's Puerto Rico-specific rate would be either the Puerto Rico-specific labor-related share of 63.2 percent or 62 percent, depending on which results in higher payments to the hospital. If the hospital has a Puerto Rico-specific wage index greater than 1.000 for FY 2016, we proposed to set the hospital's rates using a labor-related share of 63.2 percent for the 25 percent portion of the hospital's payment determined by the Puerto Rico standardized amounts because this amount would result in higher payments. Conversely, a hospital with a Puerto Rico-specific wage index of less than or equal to 1.000 for FY 2016 would be paid using the Puerto Rico-specific labor-related share of 62 percent of the Puerto Rico-specific rates because the lower labor-related share would result in higher payments.

Comment: One commenter recommended that CMS compute an alternative labor and nonlabor-related share percentage under the national standardized amount for hospitals in Puerto Rico. The commenter explained that the current labor-related share percentage of 62 percent under the national standardized amounts meets the statutory definition in section 1886(d)(3)(E) of the Act, resulting in lower payments for providers in Puerto Rico. Therefore, the commenter believed that CMS should calculate an alternative national labor-related share percentage for hospitals in Puerto Rico that is lower than 62 percent. The commenter further stated that CMS does not have empirical data that demonstrate why a lower labor share is justified. The commenter also provided the following data that shows nonlabor costs are higher in Puerto Rico. Based on data from the Council for Community and Economic Research (available on the internet at *http://www.coli.org*), the composite cost-of-living index for the MSA of San Juan, Puerto Rico out of 200 MSAs is 112.9 (where 100 is the average composite index). The commenter also noted that the measure for nonlabor items in Puerto Rico such as utilities and supermarket were 185.1 and 122.7, respectively.

Response: As we responded in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49990 through 49991), current law requires that the labor-related share for the national standardized amount be set at 62 percent for hospitals with a wage index less than or equal to 1.0000. Specifically, as discussed above, 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.

In addition, sections 1886(d)(9)(A) and (d)(9)(E)(iv) of the Act require that Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Therefore, for the portion of payment determined under the national standardized amount, Puerto Rico hospitals must follow section 1886(d)(3)(E) of the Act which requires the Secretary to use 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. For Puerto Rico, the national labor-related share is 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0000. Therefore, we are unable to change the labor-related share of 62 percent.

After consideration of public comments received, we are finalizing our proposals without modification. For FY 2016, we are continuing to use a labor-related share for the national standardized amount of 69.6 percent for

discharges occurring on or after October 1, 2015. Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2016 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site, reflect this labor-related share. For FY 2016, for all IPPS hospitals whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indexes are greater than 1.0000, for FY 2016, we are applying the wage index to a labor-related share of 69.6 percent of the national standardized amount.

Puerto Rico hospitals are paid based on 75 percent of the national standardized amounts and 25 percent of the Puerto Rico-specific standardized amounts. For Puerto Rico hospitals, the national labor-related share is 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0000. For FY 2016, we are continuing to use a labor-related share for Puerto Rico-specific standardized amounts of 63.2 percent for discharges occurring on or after October 1, 2015. We also are finalizing our proposal that the labor-related share of a hospital's Puerto Rico-specific rate for FY 2016 is either the Puerto Rico-specific labor-related share of 63.2 percent or 62 percent, depending on which results in higher payments to the hospital. The final FY 2016 Puerto Rico specific labor-related share of 63.2 percent or 62 percent is reflected in Table 1C, which is published in section VI. of the Addendum to this FY 2016 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site.

N. Changes to 3-Year Average Pension Policy and Changes to the Wage Index Timetable Regarding Pension Costs for FY 2017 and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590), we revised our policy for reporting costs of qualified defined benefit pension plans for the Medicare wage index. Under that revised policy, the pension costs that are to be included in the wage index equal a hospital's average cash contributions deposited to its defined benefit pension plan over a 3-year period or, if less than a 3-year period, the number of years that the hospital has sponsored a defined benefit plan. The 3-year average is centered on the base cost reporting period for the wage index. For example, the FY 2016 wage index is based on Medicare cost reporting periods beginning during Federal FY 2012, and reflects the average pension contributions made in a hospital's cost reporting period that began during Federal FYs 2011, 2012, and 2013. As stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51587), we centered the 3-year average on the base cost reporting period for the wage index in order to ensure that the average annual pension cost reflected in the wage index is consistent with the cost reporting period applicable to all other costs included in the index. We also stated that we did not anticipate that the use of contributions made in the period immediately following the base cost reporting period (for example, using Federal FY 2013 as one of the 3-year periods for FY 2016) would create an administrative burden because by the time the MAC would be reviewing a hospital's base cost reporting period wage data for inclusion in the subsequent year's wage index, trust account statements and general ledger reports to support the contributions should be readily available. We refer readers to the FY 2012 IPPS/LTCH PPS final rule for a complete discussion of this policy.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49987 through 49990), we finalized changes to the FY 2017 wage index timeline. We stated that we believed the timeline changes would not only improve the accuracy of the February public use file (PUF), but also would reduce the number of hospital appeals based on the February PUF. Among these changes to the wage index timeline for FY 2017 is a requirement that hospitals must request revisions to the preliminary PUF by the first week of September 2015. In response to our FY 2015 proposal to change the wage index timeline for FY 2017, a public commenter stated that the proposed FY 2017 deadline of early August 2015 did not provide enough time for hospitals to incorporate their pension data into the desk review process because the Internal Revenue Service (IRS) Form 5500 (used as the basis for reporting pension contributions for defined benefit plans) is due 7 months after the end of the plan year (July 31), with possible extensions through mid-September. In response to that comment, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989), we provided for a general deadline of early September to submit revisions to the wage index data posted in the May 2015 preliminary PUF, but provided a limited exception for submission of pension data for certain hospitals. Specifically, starting with the FY 2017 wage index, we will allow an extension for a hospital with a fiscal year begin date on or after August 15 of a year to submit its initial pension data by mid-October 2015, which would revise the preliminary PUF. We stated that we believed the majority of hospitals, which do have fiscal year begin dates prior to August 15 of a year, would be able to submit their pension data, along with the remainder of their wage index documentation, to their MACs by the beginning of September of each year, in time for the beginning of the annual wage index desk review process. We also stated that, in future rulemaking, we may consider revisions to the 3-year average pension policy that would allow all hospitals to submit their pension data at the same time. We refer readers to the FY 2015 IPPS/LTCH PPS final rule for a complete discussion of the changes to the FY 2017 wage index timeline (79 FR 49987 through 49990).

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24475), we stated that we have now reconsidered the changes made to the FY 2017 wage index timeline in light of our experience to date with the administrative aspects of the 3-year average pension policy as explained above and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590). Based on our findings, we believe that a revision of the 3-year average pension policy is warranted, beginning with the FY 2017 wage index.

Specifically, in the FY 2016 IPPS/LTCH PPS proposed rule, instead of the 3-year average being centered on the base cost reporting period for the wage index, we proposed that, for the FY 2017 wage index and all subsequent fiscal year wage indexes, the 3-year average would be based on pension contributions made during the base cost reporting period plus the prior 2 cost reporting years. For example, the FY 2017 wage index would be based on Medicare cost reporting periods beginning during Federal FY 2013. Therefore, the FY 2017 wage index would reflect the average pension contributions made in hospitals' cost reporting periods beginning during Federal FYs 2011, 2012, and 2013 (rather than Federal FYs 2012, 2013, and 2014 under the FY 2015 policy). Our proposed change in the 3-year averaging period would produce a 1-year lag in reporting pension costs relative to reporting all other costs included in the wage index and, for most hospitals, would result in the same 3-year average pension costs for both the FY 2016 and FY 2017 wage index. That is, for FY 2016, the 3-year average consists of Federal FYs 2011, 2012, and 2013, and under our proposal, the 3-year average for FY 2017 also would consist of Federal FYs 2011, 2012, and 2013. Under our proposal, the 3-year

average for FY 2018 would consist of Federal FYs 2012, 2013, and 2014.

Comment: Several commenters supported the proposed change in the 3-year averaging period for pension costs.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal without modification that, instead of the 3-year average being centered on the base cost reporting period for the wage index, for the FY 2017 wage index and all subsequent fiscal year wage indexes, the 3-year average will be based on pension contributions made during the base cost reporting period plus the prior 2 cost reporting years.

For FY 2017 only, we proposed that all hospitals submit requests to revise their previously submitted pension data by early October to mid-October (instead of the first week of September, as stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989)). We had anticipated proposing an early September deadline for all hospitals to submit revisions on all data in the preliminary PUF, including pension data. However, we realized that such a deadline would involve requiring hospitals to submit all of the revisions to pension data prior to the effective date of the final rule. Therefore, we proposed this deadline change of early October to mid-October so that all hospitals would submit revisions to their pension data by the same deadline, which should simplify the deadline for submitting those data as well as provide more time to most hospitals to submit these data. Because the pension data for FY 2017 would be the same pension data already used in FY 2016 (as mentioned above), we would expect minimal revisions to the pension data for FY 2017. Because we proposed an extension until early to mid-October for all hospitals to revise their pension data for FY 2017, we proposed to eliminate the limited exception and extension for hospitals with a fiscal year begin date of on or after August 15, as set forth in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989). The exception is no longer necessary, given the proposed use of data from older cost reports for the 3-year averaging of pension costs and the proposed extension of time for submission of revisions of pension data for all hospitals for FY 2017. For FY 2018 and subsequent fiscal years, we proposed to require that all hospitals request revisions to the preliminary PUF for all wage index issues, including submission and/or revisions of pension data, by the first week of September. The September deadline for FY 2018 and subsequent fiscal years is consistent with the deadline established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989) for the FY 2017 wage index data. Specifically, in that final rule, in response to commenters, we established the early September deadline as a feasible deadline for hospitals to request revisions to their preliminary wage and occupational mix data. In addition, we also stated that a deadline in early September would be manageable for hospitals, while also providing the MACs with the most amount of time possible to complete their desk reviews.

This proposal also would allow for a single deadline for all hospitals to submit revisions to their wage data, including their pension costs (as stated above). A single deadline is preferable because it would result in less confusion and would be easier to administer for all hospitals. In addition, the limited exception for hospitals with a fiscal year begin date of on or after August 15 would have provided administrative relief only to a minority of hospitals. Furthermore, in many cases, hospitals that participate in a systemwide pension plan or State-run retirement system have been unable to obtain timely documentation to support their allocated share of total plan contributions. We believe that a shift in the 3-year average to the base cost reporting period plus the prior 2 cost reporting years would provide all hospitals sufficient time to collect and submit their pension data by the proposed September deadline, and allow MACs to complete their desk reviews on schedule, thereby improving the accuracy of the February PUF.

The chart below includes the FY 2017 wage index timetable published in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989), except for the mid-October deadline under the limited exception and extension for submitting pension data to the MACs for hospitals with fiscal year begin dates on or after August 15, which we are eliminating in this final rule. It also includes our final policy for FY 2017 for all hospitals to request revisions to their pension data by mid-October 2015 (rather than early October as published in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989)).

FY 2017 WAGE INDEX TIMETABLE WITH DEADLINE FOR PENSION REVISIONS

Actions	Deadlines
Posting of Preliminary PUF on CMS Web site	Mid-May 2015.
Deadline for Hospitals to Request Revisions to Preliminary PUF	First week of September 2015.
Deadline for Hospitals to Request Revisions to Pension Data	Early October 2015 to Mid-October 2015.
Deadline for MACs to Complete Desk Reviews	Mid-November 2015.
Posting of January PUF on CMS Web site (formerly "February" PUF)	Late January 2016.
Deadline Following Posting of January PUF for Hospitals to Request Revisions	Mid-February 2016.
Completion of Appeals by MACs and Transmission of Final Wage Data to CMS	Mid to Late March 2016.
Deadline for Hospitals to Appeal in April	Early April 2016.
Posting of Final PUF	Late April 2016.
Deadline for Hospitals to Appeal in May	Late May 2016.
Expected Issuance of IPPS Final Rule	August 1, 2016.

For FY 2018 and subsequent fiscal years, we proposed the same timetable as in FY 2017 (adjusted for the years), except there would no longer be a separate deadline in October for submitting and/or revising pension data. Rather, all requests to submit and/or revise pension data (as well as any other requests for revisions to the preliminary PUF) for FY 2018 and subsequent fiscal years would be required to be submitted by hospitals to MACs in the first week of September each year.

Comment: Several commenters generally supported the proposed modification of the wage index timetable. Some commenters specifically supported a single deadline for revisions to preliminary wage index data, although these commenters disagreed with the September deadline for requesting revisions to the preliminary May PUF. These commenters preferred an October

deadline to allow hospitals more time to review their data.

Response: We appreciate the commenters' general support for the wage index timetable. For only FY 2017, we proposed that all hospitals submit requests to revise their previously submitted pension data by early to mid-October 2015, instead of the previous early September 2015 deadline for pension revisions finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989). This deadline of mid-October 2015 for hospitals to submit pension data revisions will simplify the deadline for submitting those data as well as provide more time to most hospitals to submit those data. We note that, on May 15, 2015, when we posted the FY 2017 preliminary PUF on the CMS Web site, we included a tentative FY 2017 timetable which included a tentative deadline of October 15, 2015, for all hospitals to request revisions to pension data and to provide documentation to support the request. This tentative FY 2017 Wage Index Development Timetable stated the following: October 15, 2015—''Per the proposed pension policy in the FY 2016 IPPS/LTCH proposed rule, deadline for all hospitals to request revisions to pension data and to provide documentation to support the request. MACs must receive the revision requests and supporting documentation by this date. In addition, this date of October 15, 2015 only applies to pension plans that are classified as defined benefit pension plans. Requests to revise data of all other types of pension plans (such as defined contribution plans) must be received by the MACs no later than September 2, 2015.'' We refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*.

Furthermore, because we proposed an extension until early to mid-October for all hospitals to revise their pension data for FY 2017, we proposed to eliminate the limited exception and extension for hospitals with a fiscal year begin date of on or after August 15, as set forth in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989). The exception is no longer necessary, given the use of data from older cost reports for the 3-year averaging of pension costs and the proposed extension of time for submission of revisions of pension data for all hospitals for FY 2017. Therefore, we are finalizing a mid-October 2015 deadline by which, for FY 2017 only, hospitals must request revisions to their pension data for pension plans that are classified as defined benefit pension plans. Requests to revise data of all other types of pension plans (such as defined contribution plans) must be received by the MACs no later than the first week of September 2015. The final FY 2017 Wage Index Development Timetable will be posted on the following CMS Web site after issuance of this FY 2016 final rule: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*.

In addition, we proposed that, for FY 2018 and subsequent fiscal years, all hospitals are required to request revisions to the preliminary PUF for all wage index issues, including submission and/or revisions of pension data, by the first week of September. We further proposed that the remainder of the timetable for FY 2017 would apply for FY 2018 and subsequent fiscal years (adjusted for the years). The September deadline, consistent with the deadline established in the FY 2015 IPPS/LTCH PPS final rule for the FY 2017 and subsequent year's wage index data (79 FR 49989), is the earliest feasible deadline for hospitals to request revisions to their preliminary wage and occupational mix data. This deadline in early September is manageable for hospitals, while it also provides the MACs with the most amount of time possible to complete their desk reviews. As such, we are finalizing that, for FY 2018 and subsequent fiscal years, all hospitals are required to request revisions to the preliminary PUF for all wage index issues, including submission and/or revisions of pension data, by the first week of September. Further, we are finalizing that the remainder of the timetable for FY 2017 will apply for FY 2018 and subsequent fiscal years (adjusted for the years).

After consideration of the public comments we received, for FY 2017 only, we are finalizing our proposals without modification that all hospitals submit requests to revise their previously submitted defined benefit pension data by early October to mid-October and eliminating the limited exception and extension for hospitals with a fiscal year begin date of on or after August 15 to submit their pension data by mid-October. We also are finalizing our proposals without modification to require that all hospitals request revisions to the preliminary PUF for all wage index issues, including submission and/or revisions of pension data, by the first week of September for FY 2018 and subsequent fiscal years, and to apply the remainder of the timetable for FY 2017 to FY 2018 and subsequent fiscal years (adjusted for the years).

The chart below summarizes the wage index timetables for FY 2018 and subsequent fiscal years.

WAGE INDEX TIMETABLE

Actions	Deadlines
Posting of Preliminary PUF on CMS Web site	Mid-May (about 16 months prior to the effective date of wage index).
Deadline for Hospitals to Request Revisions to Preliminary PUF (including revision requests for all pension data).	First week of September (about 13 months prior to the effective date of wage index).
Deadline for MACs to Complete Desk Reviews	Mid-November (about 11 months prior to the effective date of wage index).
Posting of January PUF on CMS Web site (formerly ''February'' PUF)	Late January (about 9 months prior to the effective date of wage index).
Deadline Following Posting of January PUF for Hospitals to Request Revisions.	Mid-February (about 8 months prior to the effective date of wage index).
Completion of Appeals by MACs and Transmission of Final Wage Data to CMS.	Mid to Late March (about 7 months prior to the effective date of wage index).
Deadline for Hospitals to Appeal in April	Early April (about 6 months prior to the effective date of wage index).
Posting of Final PUF	Late April (about 6 months prior to the effective date of wage index).
Deadline for Hospitals to Appeal in May	Late May (about 5 months prior to the effective date of wage index).
Expected Issuance of IPPS Final Rule	August 1 (2 months prior to the effective date of wage index).
Effective date of the wage index	October 1, beginning of the fiscal year.

O. Clarification of Allocation of Pension Costs for the Wage Index

As discussed in section III.N. of the preamble of this final rule, the pension cost to be included in the Medicare wage index equals a hospital's average cash contributions deposited to its defined benefit pension plan over a 3-year period. Since implementing this policy, we have become aware of some confusion with respect to how hospitals are to compute the 3-year average when allocating their pension costs on the Medicare cost report if a hospital participates in a pension plan or retirement system that also covers other entities. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24477), we clarified that if a hospital participates in a pension plan or retirement system that also covers other entities, the hospital must report its respective 3-year average pension cost (or prefunding balance) reflecting only the hospital's allocated share of total plan contributions, and *not* including any share of pension costs of other entities. For each hospital, this is accomplished by first determining the hospital's allocated portion of pension contribution for each year of the 3-year average, and then computing the 3-year average for that hospital based only on that hospital's respective allocated pension contributions. This is consistent with the regulations at 42 CFR 413.24(a), which state, in pertinent part, that providers must provide adequate cost data based on their financial and statistical records. Therefore, a provider may not claim as an allowable cost the costs of services associated with another entity. It is not appropriate to compute the 3-year average (or prefunding balance) based on the total contributions made to the plan by all participating entities and then determine a hospital's allocated portion of the 3-year average cost (or prefunding balance) because there are instances in which the 3-year average could be skewed because a hospital may be including pension costs from another entity in its 3-year average. Specifically, if the allocated percentage of total plan contributions for one or more of the participating entities changes during the 3-year average, the average will be skewed. The allocated percentage to each entity can change due to mergers, changes in plan coverage, or other factors. We also note that the allocation of contributions between the various entities participating in a pension plan or pension system should agree with the methodology used for plan reporting purposes and/or financial statement purposes, and the methodology used should be applied consistently over time. Furthermore, if wage index reporting is required for two or more hospitals covered under the same pension plan or retirement system, those hospitals should ensure that the allocation of plan contributions for each reporting period is determined on a consistent basis to avoid duplicate reporting of costs.

We did not received any public comments on this clarification that was included the FY 2016 IPPS/LTCH PPS proposed rule.

IV. Other Decisions and Changes to the IPPS for Operating Costs and Indirect Medical Education (IME) Costs

A. Changes in the Inpatient Hospital Update for FY 2016 (§ 412.64(d))

1. FY 2016 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 operating costs by a factor called the ''applicable percentage increase.'' For FY 2016, we are setting the applicable percentage increase by applying the adjustments listed below in the same sequence as we did for FY 2015. 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 (1) 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; (2) a 66⅔ percent reduction to 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; (3) an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment); and (4) an additional reduction of 0.2 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 2016 adjustment of 0.2 percentage point may result in the applicable percentage increase being less than zero. Under section 1886(b)(3)(B)(ix) of the Act, the reduction to three-quarters of the applicable percentage increase for those hospitals that are not meaningful EHR users will increase to 100 percent for FY 2017 and subsequent fiscal years.

We note that, in compliance with section 404 of the MMA, in the FY 2014 IPPS/LTCH PPS final rule, we replaced the FY 2006-based IPPS operating and capital market baskets with the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2014. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49993 through 49996), we continued to use the FY 2010-based IPPS operating and capital market baskets for FY 2015 and the labor-related share of 69.6 percent, which is based on the FY 2010-based IPPS market basket. For FY 2016, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24477), we proposed to continue using the FY 2010-based IPPS operating and capital market baskets and the labor-related share of 69.6 percent, which is based on the FY 2010-based IPPS market basket. We did not receive any public comments on this proposal and, therefore, for FY 2016, will continue to use the FY 2010-based IPPS operating and capital market baskets and the labor-related share of 69.6 percent.

Based on the most recent data available for the FY 2016 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we proposed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24477) to base the FY 2016 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Insight, Inc.'s (IGI's) first quarter 2015 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2014, which was estimated to be 2.7 percent. We proposed that if more recent data became subsequently 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 2016 market basket update and the MFP adjustment in this final rule.

Based on updated data for this FY 2016 IPPS/LTCH PPS final rule, that is, the IGI's second quarter 2015 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through first quarter 2015, we estimate that the FY 2016 market basket update used to determine the applicable

percentage increase for the IPPS is 2.4 percent.

For FY 2016, 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 discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24477 through 24478) that there are four possible applicable percentage increases that can be applied to the standardized amount. Based on more recent data described above, we determined final applicable percentage increases to the standardized amount for FY 2016, as specified in the table below.

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 Web site 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 described in the FY 2012 IPPS/LTCH PPS final rule, in order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the FY 2012 IPPS/LTCH PPS final rule, we identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series.

Beginning with the FY 2016 rulemaking cycle, as discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24478), the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the FY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on our Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*. Although we discuss the IGI changes to the MFP proxy series in the FY 2016 IPPS/LTCH PPS proposed rule and in this final rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

For FY 2016, we proposed an MFP adjustment of 0.6 percentage point (80 FR 24478). Similar to the market basket update, for the proposed rule, we used the most recent data available to compute the MFP adjustment. As noted above, we proposed that if more recent data became subsequently available, we would use such data, if appropriate, to determine the FY 2016 market basket update and MFP adjustment in this FY 2016 IPPS/LTCH PPS final rule.

Based on the most recent data available for this final rule, which is IGI's second quarter 2015 forecast (with historical data through first quarter 2015), the MFP adjustment is 0.5 percentage point for FY 2016.

Comment: One commenter supported the proposed FY 2016 IPPS market basket increase of 1.1 percent, after applicable adjustments, to update the IPPS payments for FY 2016 based upon the most current data available. The commenter urged CMS to conduct regular payment impact analysis to ensure appropriate payment levels for inpatient services.

Response: We appreciate the commenter's support of the FY 2016 market basket update under the IPPS. As noted, for this final rule, we are using updated data to estimate the FY 2016 market basket update and MFP adjustment used to determine the applicable percentage increase for the IPPS. We also note that, in each proposed and final rule, we include a payment impact analysis.

Comment: One commenter recognized that some of the proposed adjustments of the annual Medicare inpatient rate update are statutory requirements but, nevertheless, expressed disappointment in the small proposed increase of 0.3 percent after the various adjustments. The commenter further stated that, from the perspective of providers, Medicare is continually asking them to do more, such as report more data, provide care in different ways, and invest in more health care information technology. The commenter believed the continual small increases in Medicare payments suggest that Medicare is not interested in helping to pay for any of these improvements. The commenter stated that urban safety-net hospitals are continually stepping up to meet these challenges and urged CMS to join them in stepping up by showing a greater willingness to share the cost of doing so.

Response: We acknowledge the commenter's concern regarding the increased reporting requirements coupled with the MFP adjustment under section 1886(b)(3)(B)(xi) of the Act and the 0.2 percentage point statutory adjustment under section 1886(b)(3)(B)(xii) of the Act. However, as the commenter mentioned, we are required to determine the applicable percentage increase based on the statutory requirements discussed above.

Comment: One commenter stated that the increase to the operating inpatient rates of 1.1 percent omits the 2-percent automatic reductions or sequester required by the Budget Control Act of 2011 (Pub. L. 112–25). The commenter stated the real payment update to acute care hospitals when all of the quality adjustments are considered is approximately –1.0 percent. The commenter further stated that hospitals will be receiving less for the same services in FY 2016 when compared to payment rates in FY 2015. The commenter recommended that the 2-percent sequester reduction be included in the calculation of the annual percentage update because it is a real line item reduction to hospital IPPS payments. The commenter believed that the inclusion of the sequestration would lead to an accurate portrayal of the annual Medicare payment update to hospitals.

Response: We appreciate the commenter's concerns. However, the sequestration reduction is not a statutory reduction to the applicable percentage increase (it is a 2-percent reduction to overall payments) and, therefore, is not included in the calculation of the applicable percentage increase.

As stated in the proposed rule, we proposed to use more recently available data to determine the final market basket update and the multifactor productivity adjustment. We did not receive any public comments on this proposal. Therefore, for this final rule, we are finalizing a market basket update of 2.4 percent and an MFP adjustment of 0.5 percentage point based on more recently available data.

Based on the most recent data available for this final rule as described above, we have determined four final applicable percentage increases to the standardized amount for FY 2016, as specified in the table below.

FINAL FY 2016 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2016	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
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.6	−0.6
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−1.2	0.0	−1.2
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Final Applicable Percentage Increase Applied to Standardized Amount	1.7	0.5	1.1	−0.1

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24478), we proposed to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2016 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we proposed to modify paragraph (vi) of § 412.64(d)(1) to include the applicable percentage increase to the FY 2016 operating standardized amount. We did not receive any public comments on this proposal. Therefore, we are finalizing our proposed revisions to the regulations at § 412.64(d).

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. We note that 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).

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24478), for FY 2016, we proposed the following updates to the hospital-specific rates applicable to SCHs: An update of 1.9 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 1.225 percent for a hospital that fails to submit quality data and is a meaningful EHR user; an update of 0.55 percent for a hospital that submits quality data and is not a meaningful EHR user; and an update of −0.125 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. We note that at the time of the development of the FY 2016 IPPS/LTCH PPS proposed rule, the MACRA had yet to be signed into law and therefore we did not explicitly address the update of the hospital-specific rates for FY 2016 for MDHs. However, as noted, under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific rates is the same for both MDHs and SCHs and is equal to 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 mentioned above, for the FY 2016 proposed rule, we used IGI's first quarter 2015 forecast (with historical data through fourth quarter 2014) of the FY 2010-based IPPS market basket update. Similarly, we used IGI's first quarter 2015 forecast of the MFP adjustment. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24478), we proposed that if more recent data became subsequently 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 update for SCHs in this final rule. We did not receive any public comments with regard to this proposal and, therefore, are finalizing the proposal to determine the update to the hospital-specific rates for SCHs and MDHs in this final rule using the most recent data available.

As discussed above, based on more recent data for IGI's second quarter 2015 forecast of the FY 2010-based IPPS market basket update with historical data through first quarter 2015, we estimate that the FY 2016 market basket update used to determine the update factor for this final rule for the hospital-specific rates of SCHs and MDHs is 2.4 percent. Similarly, for this final rule, we used IGI's second quarter 2015 forecast of the MFP adjustment, which is estimated at 0.5 percentage point for FY 2016. Accordingly, we are finalizing the following updates to the hospital-specific rates applicable to SCHs and MDHs: An update of 1.7 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 1.1 percent for a hospital that fails to submit quality data and is a meaningful EHR user; an update of 0.5 percent for a hospital that submits quality data and is not a meaningful EHR user; and an update of −0.1 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. FY 2016 Puerto Rico Hospital Update

Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 1886(d)(9)(C)(i) of the Act is the basis for determining the applicable percentage increase applied to the Puerto Rico-specific standardized amount. Section 401(c) of Public Law 108–173 amended section

1886(d)(9)(C)(i) of the Act, which states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24479), we proposed an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 1.9 percent for FY 2016. For the proposed rule, we used the first quarter 2015 forecast of the FY 2010-based IPPS market basket update with historical data through fourth quarter 2014. We proposed that if more recent data became subsequently available, we would use such data, if appropriate, to determine the final FY 2016 applicable percentage increase for this final rule. We note that the provisions of section 1886(b)(3)(B)(viii) of the Act, which specify the adjustments to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, and the provisions of section 1886(b)(3)(B)(ix) of the Act, which specify the adjustments to the applicable percentage increase for ''subsection (d)'' hospitals that are not meaningful EHR users, are not applicable to hospitals located in Puerto Rico.

Similarly, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24479), we used IGI's first quarter 2015 forecast of the MFP adjustment. We proposed that if more recent data became subsequently available, we would use such data, if appropriate, to determine the MFP adjustment for the final rule.

We did not receive any public comments concerning our proposal. Therefore, using the most recent data available, for FY 2016, we are finalizing an applicable percentage increase to the Puerto Rico-specific operating amount of 1.7 percent (which reflects a FY 2016 estimate of the FY 2010-based IPPS market basket rate-of-increase of 2.4 percent, less an MFP adjustment of 0.5 percentage point and less an additional reduction of 0.2 percentage point as required by section 1886(b)(3)(B)(xii) of the Act). As we noted above, for the proposed rule, we used the first quarter 2015 forecast of the FY 2010-based IPPS market basket update and MFP with historical data through fourth quarter 2014. For this final rule, we used the most recent data available, which is IGI's second quarter 2015 forecast (with historical data through first quarter 2015).

B. Rural Referral Centers (RRCs): 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), CMS reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, CMS 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 national median CMI value for FY 2016 is based on the CMI values of all urban hospitals nationwide, and the regional median CMI values for FY 2016 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 values are based on discharges occurring during FY 2014 (October 1, 2013 through September 30, 2014), and include bills posted to CMS' records through March 2015.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24479), we proposed 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,

2015, they must have a CMI value for FY 2014 that is at least—

- 1.6075; 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. (We refer readers to the table set forth in the FY 2016 IPPS/LTCH PPS proposed rule at 80 FR 24480.)

The final CMI values for FY 2016 are based on the latest available data (FY 2014 bills received through March 2015). 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, 2015, they must have a CMI value for FY 2014 that is at least—

- 1.6082; 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 final median CMI values by region are set forth in the following table.

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.3737
2. Middle Atlantic (PA, NJ, NY)	1.4500
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5035
4. East North Central (IL, IN, MI, OH, WI)	1.5104
5. East South Central (AL, KY, MS, TN)	1.4184
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.5855
7. West South Central (AR, LA, OK, TX)	1.6276
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7075
9. Pacific (AK, CA, HI, OR, WA)	1.6168

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24480), for FY 2016, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2013 (that is, October 1, 2012 through September 30, 2013), which are the latest cost report data available at the time the proposed rule was developed.

We proposed 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, 2015, must have, as the number of discharges for its cost reporting period that began during FY 2013, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2016 IPPS/LTCH PPS proposed rule at 80 FR 24480.)

Based on the latest discharge data available at this time (that is, based on FY 2013 cost report data), the final median number of discharges for urban hospitals by census region are set forth in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	7,462
2. Middle Atlantic (PA, NJ, NY)	10,594
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,233
4. East North Central (IL, IN, MI, OH, WI)	7,992
5. East South Central (AL, KY, MS, TN)	7,672
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,857
7. West South Central (AR, LA, OK, TX)	5,490
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,046
9. Pacific (AK, CA, HI, OR, WA)	8,797

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, under this final rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

C. Indirect Medical Education (IME) Payment Adjustment Factor for FY 2016 (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2016, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2016 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.

We did not receive any public comments on this provision. As noted above, the IME formula multiplier is specified in statute and is 1.35 for FY 2016.

D. FY 2016 Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) (§ 412.106)

1. Background

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 DSH statutory references (under section 1886(d)(5)(F) of the Act) to ''days'' apply only to hospital acute care inpatient days. Regulations located at § 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).

2. Impact on Medicare DSH Payment Adjustment of the Continued Implementation of New OMB Labor Market Area Delineations

As discussed in section III.G. of the preamble of this final rule, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951) we implemented the revised OMB labor market area delineations (which are based on 2010 Decennial Census data) for the FY 2015 wage index. (In this final rule, we refer to these revised OMB labor market area delineations as the ''new OMB delineations.'') We stated that this implementation would have an impact on the calculation of Medicare DSH payments to certain hospitals. Hospitals that are designated as rural with less than 500 beds and that are not rural referral centers (RRCs) are subject to a maximum DSH payment adjustment of 12 percent. Accordingly, hospitals with less than 500 beds that were in urban counties that became rural when we adopted the new OMB delineations, and that did not become RRCs, are subject to a maximum DSH payment adjustment of 12 percent. (We note that urban hospitals are only subject to a maximum DSH payment adjustment of 12 percent if they have less than 100 beds.)

Under the regulation at 42 CFR 412.102, a hospital located in an area that is reclassified from urban to rural, as defined in the regulations, may receive an adjustment to its rural Federal payment amount for operating costs for 2 successive fiscal years. Specifically, the regulations state that, in the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two-thirds of the difference between the DSH payments as applicable to the hospital before its redesignation from urban to rural and the DSH payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one-third of the difference between the DSH payments applicable to the hospital before its redesignation from urban to rural and the DSH payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural.

For the purposes of ratesetting, calculating budget neutrality, and modeling payment impacts for this FY 2016 final rule, for any hospital that was previously urban but changed to rural status in FY 2015 as a result of the adoption of the new OMB labor market area delineations, in the FY 2016 IPPS/LTCH PPS proposed rule, we proposed to model its DSH payments such that the payment equals the amount of the rural DSH payments plus one-third of the difference between the urban DSH payments and the rural DSH payments.

We did not receive any public comments on our proposal.

3. Payment Adjustment Methodology for Medicare Disproportionate Share Hospitals (DSHs) Under Section 3133 of the Affordable Care Act

a. General Discussion

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 new section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. For purposes of this final rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.

Medicare DSH payments are calculated under a statutory formula that considers the hospital's Medicare utilization attributable to beneficiaries who also receive Supplemental Security Income (SSI) benefits, and the hospital's Medicaid utilization. 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 under age 65 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 a disproportionate share hospital payment 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 a 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 Medicare Payment Advisory Commission in its March 2007 Report to the 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 each 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 FYs 2014 through 2017, 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, determined by comparing the percent of such individuals who are 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), minus 0.1 percentage point for FY 2014, and minus 0.2 percentage point for FYs 2015 through 2017. For FYs 2014 through 2017, the baseline for the estimate of the change in uninsurance is fixed by the most recent estimate of the Congressional Budget Office before the final vote on the Health Care and Education Reconciliation Act of 2010, which is contained in a March 20, 2010 letter from the Director of the Congressional Budget Office to the Speaker of the House. (The March 20, 2010 letter is available for viewing on the following Web site: *http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf*.)

For FY 2018 and subsequent 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 are 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 are 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. Therefore, for FY 2018 and subsequent years, the statute provides some greater flexibility in the choice of the data sources to be used for the estimate of the change in the percent of uninsured individuals.

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 is available which is 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 that 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 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.

b. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As indicated 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 would 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 will be paid under the Maryland All-Payer Model. However, under the Maryland All-Payer Model, Maryland hospitals still are not paid under the IPPS. Therefore, they remain ineligible to receive empirically justified Medicare DSH payments or uncompensated care payments under section 1886(r) of the Act.

- *SCHs* that are paid under their hospital-specified 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).
- *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 used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. We note that at the time of the development of the FY 2016 IPPS/LTCH PPS proposed rule, the MDH Program was to be in effect for discharges on or before March 31, 2015, only. Section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10, enacted April 16, 2015, extended the MDH program for discharges on or after April 1, 2015, through September 30, 2017. (We refer readers to the interim final rule with comment period at section IV.L.3. of the preamble of this document for a full discussion of the extension of the MDH Program.) Because MDHs are paid based on the IPPS Federal rate, for FY 2016, MDHs will continue to be eligible to receive Medicare DSH payments and uncompensated care payments if their disproportionate patient percentage is at least 15 percent. We will apply the same process to determine MDH eligibility for Medicare DSH and uncompensated care payments, as we do for all other IPPS hospitals, through September 30, 2017. Moreover, 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 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 have elected to participate in the Bundled Payments for Care Improvement initiative* continue to be paid under the IPPS (77 FR 53342) and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments (78 FR 50625 and 79 FR 50008).
- *Hospitals participating in the Rural Community Hospital Demonstration Program* under section 410A of the Medicare Modernization Act do not receive DSH payments and, therefore, are excluded from receiving empirically justified Medicare DSH payments and uncompensated care payments under the new DSH payment methodology (78 FR 50625 and 79 FR 50008). There are 17 hospitals currently participating in the demonstration.

c. 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 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 Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html*.

d. Uncompensated Care Payments

As we have 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 FY 2014 and FY 2015, and our proposed and final policies for FY 2016.

(1) Calculation of Factor 1 for FY 2016

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 it is a factor equal to the difference between (i) the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) if this section did not apply for such fiscal year (as estimated by the Secretary); and (ii) 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 payment 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 2015, in order to determine Factor 1 in the uncompensated care payment formula for FY 2016, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24484), we proposed 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). Under this policy, Factor 1 is determined 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 section 1886(r)(1) of the Act through rulemaking. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2016.

Therefore, in order to determine the two elements of Factor 1 (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), in FYs 2014 and 2015, we used the most recently available projections of Medicare DSH payments for the applicable 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 Factor 1 and modeling the impact of this provision for the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24484), we used the Office of the Actuary's February 2015 Medicare DSH estimates, which are based on data from the December 2014 update of the Medicare Hospital Cost Report Information System (HCRIS), 2012 cost report data provided to CMS by IHS hospitals, and the FY 2015 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2015 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are not subject to the provisions of section 1886(r) of the Act, these hospitals were excluded from the February 2015 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified DSH payment (or 25 percent of DSH payments that would be made without regard to section 1886(r)), Maryland hospitals participating in the Maryland All-Payer Model and hospitals participating in the Rural Community Hospital Demonstration that do not receive DSH payments also are excluded from the Office of the Actuary's Medicare DSH estimates.

Using the data sources discussed above, the Office of the Actuary applies inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The February 2015 Office of the Actuary estimate for proposed Medicare DSH payments for FY 2016, without regard to the application of section 1886(r)(1) of the Act, was approximately $13.338 billion. Therefore, based on the February 2015 estimate, the estimate for empirically justified Medicare DSH payments for FY 2016, with the application of section 1886(r)(1) of the Act, was $3.335 billion (25 percent of the total amount estimated). 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 the proposed rule, we proposed that Factor 1 for FY 2016 would be $10,003,425,327.39 ($13,337,900,436.52 minus $3,334,475,109.13). We invited public comments on our proposed calculation of Factor 1 for FY 2016.

Comment: A number of commenters supported CMS' methodology for determining Factor 1 and the proposed Factor 1 for FY 2016.

Response: We appreciate the commenters' support.

Comment: A number of commenters asked for greater transparency around the methodology used by the Office of the Actuary to estimate aggregate DSH payments that would have been paid absent implementation of the Affordable Care Act, particularly transparency in the calculation of estimated DSH payments for purposes of Factor 1. The commenters urged CMS to clarify the methodology used to make these projections and to provide additional information related to them. The commenters also requested that this information be provided in advance of publication of the IPPS final rule and, in the future, in proposed rules each year. The commenters stated that hospitals do not have sufficient information to understand or replicate the relevant projections and estimates for Factor 1.

Many commenters highlighted that one of the assumptions (the assumption shown in ''Other'' column) used in determining the proposed Factor 1 for FY 2016 has a substantial negative effect on hospitals, and requested more explanation for that assumption as well as a reassessment of the assumption. They pointed out that this assumption had previously, according to CMS, included the impact of only IPPS discharges and the impact of DSH payments increasing or decreasing at a different rate than other IPPS payments. The commenters expressed concern that the ''Other'' column changed from 1.0355 in the FY 2015 IPPS/LTCH PPS final rule to 0.9993 in the FY 2016 IPPS/LTCH PPS proposed rule. The commenters noted that the explanation offered in the FY 2015 IPPS/LTCH PPS final rule discussed Medicaid enrollment and utilization patterns and that this did not appear to explain the change in the variable in the FY 2016 IPPS/LTCH PPS proposed rule. Some commenters pointed out that, to some extent, the ''Other'' assumption is affected by the ''Discharge'' assumption, and that they believed discharges are decreasing faster than what was taken into consideration in the FY 2015 IPPS/LTCH PPS final rule. In other words, they believed that the trend information used to determine the ''Discharge'' assumption may be resulting in a lower number for the ''Other'' assumption.

One commenter stated that CMS does not disclose how discharge data are adjusted by a completion factor. One commenter also pointed out that the values for the assumptions regarding discharges and case-mix across FY 2014, FY 2015, and FY 2016 are relatively similar, while the value for the ''Other'' assumption has changed. The commenters requested that CMS also share detailed calculations of the discharge and case-mix values.

Several commenters believed that the ''Other'' assumption should reflect the changes in DSH payments that would result from the Medicaid and CHIP expansion. Other commenters asked CMS to explain how the Medicaid and CHIP expansion is accounted for in the Factor 1 estimate. The commenters stated that the additional Medicaid and CHIP enrollment estimated for 2014 through 2016 by CBO in a February 2014 report represents a 32-percent increase in this population. The commenters stated that they had reviewed other data, including the ASPE Issue Brief entitled ''Impact of Insurance Expansion on Hospital Uncompensated Care Costs in 2014,'' that indicate that Medicaid enrollment and utilization have increased. The commenters believed that Factor 1 is too low because it does not take this increase into consideration appropriately. They noted that CMS has responded to similar comments in prior rulemaking by stating that ''the increase due to Medicaid expansion is not as large as commenters contended due to the actuarial assumption that the new enrollees are healthier than the average Medicaid recipient, and, therefore, use fewer hospital services.'' However, the commenters asserted that CMS provided no support for this contention and that CMS should have enrollment and/or utilization information from Medicaid expansion programs. Furthermore, the commenters stated that they believed CMS did not take into consideration any one-time increase in utilization resulting from the new Medicaid enrollment and the previously unmet health care needs of that population. These commenters believed that, in the early years of Medicaid expansion, such an increase in utilization would be more logical than CMS' assertion that new Medicaid enrollees would use fewer hospital services.

Several commenters believed that it would be appropriate to adjust the ''Other'' assumption in a manner that supports safety-net hospitals in order to reflect the growing number of hospitals that are becoming eligible for DSH. Based on this belief, the commenters expressed concern about the sustainability of continued reductions to aggregate uncompensated care payments. The commenters noted that, as insurance coverage increases, the aggregate amount available for uncompensated care payments will decline and thus reduce the amount of payments to be distributed to help cover the cost of uncompensated care. The commenters further noted that hospitals in States that have not expanded Medicaid are not experiencing a decrease in uncompensated care costs and that reductions in Medicare DSH payments are detrimental to these hospitals. Some commenters noted the reductions in payments they would experience due to CMS' uncompensated care proposal in totality.

Several commenters believed there was incomplete information in the FY 2016 IPPS/LTCH PPS proposed rule regarding the ''completion factor'' and requested further detail. One commenter believed that the growth rates in DSH payments are higher than the current data indicate because the completion factor for the cost reports in HCRIS for 2012 and 2013 is low. Specifically, the commenter shared an analysis that showed that approximately one-half of the 2012 cost reports contained adjusted Medicaid days data and approximately one-fifth of the 2013 cost reports contained adjusted Medicaid days data. The commenter showed the results of a longitudinal analysis between December 2012 and March 2015 using HCRIS data that demonstrated that Medicaid days increased between when 2010, 2011, and 2012 cost reports were filed and March 2015, regardless of the status of the cost report settlement process (for example, amended, reopened, settled without audit, or settled with audit). The range of increase shown by the commenter's analysis was between 0.3 percent and 3.7 percent. The commenter stated that in its longitudinal analysis of HCRIS data between December 2012 and March 2015, it further examined DSH payments reported in HCRIS and found that payments increased on average 1.1 percent over the 2-year period.

One commenter requested that CMS use the most recent 2012 cost report data in its estimate of Factor 1. The commenter stated that problems in obtaining accurate data for Medicaid days can lead to underreporting in the initial submission of the Medicare cost report and that this delay can also affect the DSH payment calculated in the cost report. Therefore, the commenter requested that CMS revise its estimate of the 2012 DSH payments in the final rule using the latest available update of the 2012 Medicare cost report data.

Commenters wanted to better understand the changes in the estimate of aggregate DSH payments that would have been paid absent implementation of the Affordable Care Act over time and wanted to be able to replicate the figures. The commenters believed that transparency is critical because the statute precludes judicial review of the estimates for purposes of determining the three factors used in computing uncompensated care payments and because they understand that these estimates will not be revised or updated after the final rule.

Response: Factor 1 is not estimated in isolation. The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Mid-Session Review of the President's Budget. For additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget Web site at: *https://www.whitehouse.gov/omb/budget*. For additional information on the specific economic assumptions used in the Midsession Review of the President's FY 2016 Budget, we refer readers to the ''Midsession Review of the President's FY 2016 Budget'' available on the Office of Management and Budget Web site at: *https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/16msr.pdf*, under ''Economic Assumptions''. For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2014 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2014.pdf* under ''Actuarial Methodology and Principal Assumptions for Cost Estimates''.

As we did in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50010), later in this section we provide additional information regarding the data sources, methods, and assumptions employed by the actuaries in determining the Office of the Actuary's updated estimate of Factor 1 for FY 2016. We believe that this discussion addresses the methodological concerns raised by commenters regarding the various assumptions used in the estimate, including the ''Other'' and ''Discharges'' assumptions and also provides

additional information regarding how we address the Medicaid and CHIP expansion. However, we note that, with regard to the commenters' questions and concerns on the completion factor for 2012 and 2013 cost reports in HCRIS, the Office of the Actuary assumed a discharge completion factor of 99 percent for FY 2013 and 98 percent for FY 2014. Similarly, the Office of the Actuary assumed that case-mix was stabilized at the time of the estimate and no additional completion factor adjustment was needed. These assumptions are consistent with historical patterns. Regarding the commenters' assertion that Medicaid expansion is not adequately accounted for in the ''Other'' column, we note that the Office of the Actuary assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion is 50 percent of the average per capita of the pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. We have found this assumption to be consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

In response to the commenters who requested that we adjust the ''Other'' assumption to reflect the growing number of DSH hospitals in a manner that supports safety-net hospitals, particularly in States that do not have a Medicaid or CHIP expansion, we note that our proposed methodology includes assumptions regarding how DSH payments will increase in aggregate, regardless of how many hospitals qualify for DSH payments. Furthermore, we believe that, while the statute provides the Secretary with discretion to make an estimate, the statute is clear that the computation of Factor 1 begins with an aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) if this section did not apply for such fiscal year. In our view, the most appropriate way to do so is to project to the best of our abilities how payments will actually change in aggregate, based on the programs and policies that will be in effect during the fiscal year.

We agree with the commenters that CMS should use the most recent update of the 2012 Medicare cost report data available to us and note that the Office of the Actuary has done so in using the March 2015 extract of 2012 cost reports in HCRIS for this final rule.

Comment: Some commenters requested that, in light of their concerns about the data sources and methods used to estimate Factor 1, CMS adopt a process of reconciling the initial estimates of Factor 1 with actual data for the payment year in conjunction with the final settlement of hospital cost reports for the applicable year. Specifically, the commenters asserted that later data that become available after the end of a Federal fiscal year but before final DSH payment determinations are made in notices of program reimbursement would result in Factor 1 estimates that are more accurate than estimates made before the start of a Federal fiscal year. The commenters believed that a ''true-up approach'' would resolve most of what they characterize as ''discrepancies between estimates and reality.'' The commenters stated that generalized concerns about administrative ease and finality are not justifications for the use of advance estimates that are inaccurate due to ''inherent uncertainties'' in making projections of DSH payments in an ''early, post-ACA environment.'' As an example of a way by which this ''true-up'' could occur, one commenter requested the CMS update the calculation of the discharge factor used to calculate Factor 1 in an interim final rule.

Response: We continue to believe that applying our best estimates prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010). As we noted in the FY 2014 IPPS/LTCH PPS final rule, we do not know the aggregate Medicare DSH payment amount that would be paid for each Federal fiscal year until the time of cost report settlements, which occur several years after the end of the fiscal year. Furthermore, the statute provides that Factor 1 shall be determined based on estimates of the aggregate amount of DSH payments that would be made in the absence of section 1886(r) of the Act and the aggregate amount of empirically justified DSH payments that are made under section 1886(r)(1) of the Act. We believe that, in affording the Secretary the discretion to estimate the amount of these payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability in payments and sought to avoid a situation in which the uncompensated care payments would be subject to change over a period of a number of years. Accordingly, we do not agree with the commenters that we should establish a process for reconciling our estimates of Factor 1. We note that, in reviewing the Office of the Actuary's prior estimates for DSH payments compared to actual experience, from FY 2005 to FY 2016, the original estimates have been higher than actual experience for 8 of the 12 years and lower than actual experience in only 4 years.

Comment: Some commenters indicated that the estimated DSH payments do not account for the impact of the decision in *Allina* v. *Sebelius,* by excluding Medicare Advantage days from the SSI ratio and including dual eligible Medicare Advantage days in the Medicaid fraction, thus understating the estimate of Factor 1.

Response: We do not believe the *Allina* decision has any bearing on our estimate of Factor 1 for FY 2016. The holding in *Allina* addresses traditional DSH payments made to a group of providers between 2004 and 2010. Moreover, the decision did not address the FY 2014 IPPS/LTCH PPS final rule (78 FR 50614 through 50620) in which we readopted the policy of counting Medicare Advantage days in the SSI ratio for FY 2014 and all subsequent fiscal years. In its estimate of Factor 1 for FY 2016 for the FY 2016 IPPS/LTCH PPS proposed rule, the Office of the Actuary was making an estimate of difference between the aggregate amount of DSH payments that would be made under section 1886(d)(5)(F) of the Act in FY 2016 if section 1886(r) of the Act did not apply and the aggregate amount of empirically justified DSH payments that will be made to hospitals in FY 2016 under section 1886(r)(1) of the Act. Thus, although the Office of the Actuary used 2012 cost report data in making this estimate, it also applied inflation adjustments and assumptions in order to estimate Medicare DSH payments for FY 2016. Accordingly, consistent with § 412.106(b)(2), as readopted in the FY 2014 IPPS/LTCH PPS final rule, in estimating DSH payments for FY 2016, the Office of the Actuary did not remove patients enrolled in Medicare Advantage plans from SSI ratios or make any other adjustments to the hospital cost report data for 2012 included in the HCRIS database. We believe this methodology is consistent with the statute and regulations.

After consideration of the public comments we received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2016. Using this methodology, below we discuss the resulting Factor 1 amount for FY 2016.

To determine Factor 1 and to model the impact of this provision for FY 2016, we used the Office of the Actuary's July 2015 Medicare DSH estimates based on data from the March 2015 update of 2012 cost report data included in HCRIS, 2012 cost report data provided

to CMS by IHS hospitals, and the FY 2015 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2015 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are not subject to the provisions of section 1886(r) of the Act, these hospitals were excluded from the July 2015 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified DSH payment (or 25 percent of DSH payments that would be made without regard to section 1886(r)), Maryland hospitals participating in the Maryland All-Payer Model and hospitals participating in the Rural Community Hospital Demonstration that do not receive DSH payments also are excluded from the Office of the Actuary's Medicare DSH estimates.

Using the data sources discussed above, the Office of the Actuary applied inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The July 2015 Medicare DSH estimate for FY 2016, without regard to the application of section 1886(r)(1) of the Act, is $13,411,096,528.05. Based on this estimate, the estimate for empirically justified Medicare DSH payments for FY 2016, with the application of section 1886(r)(1) of the Act, is $3,352,774,132.01 (25 percent of the total amount estimated). 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, for this final rule, Factor 1 for FY 2016 is $10,058,322,396.04 ($13,411,096,528.05 minus $3,352,774,132.01). Below we provide additional detail regarding the development of this estimate.

The Office of the Actuary's estimates for FY 2016 begin with a baseline of $11.637 billion in Medicare DSH expenditures for FY 2012. The following table shows the factors applied to update this baseline through the current estimate for FY 2016.

FACTORS APPLIED FOR FY 2013 THROUGH FY 2016 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2012 BASELINE

FY	Update	Discharge	Case-mix	Other	Total	Estimated DSH payments (in billion)
2013	1.028	0.9844	1.014	1.0137	1.040189	$12.105
2014	1.009	0.9634	1.015	0.9993	0.985961	11.935
2015	1.014	0.9893	1.005	1.0512	1.059784	12.648
2016	1.009	1.0006	1.005	1.045	1.060313	13.411

In this table, the discharge column shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FYs 2013 and 2014 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2015 is based on preliminary data for 2015. The discharge figure for FY 2016 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare FFS and also MA plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FYs 2013 and 2014 are based on actual data adjusted by a completion factor. The FY 2015 and FY 2016 increases 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, various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the increase in rates for the *Cape Cod* litigation and the reduction 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 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 percentage adjustment	Total update percentage
2013	2.6	−0.1	−0.7	+1.0	2.8
2014	2.5	−0.3	−0.5	−0.8	0.9
2015	2.9	−0.2	−0.5	−0.8	1.4
2016	2.4	−0.2	−0.5	−0.8	0.9

Note: All numbers are based on the Midsession Review of FY 2016 Budget projections.

(2) Calculation of Factor 2 for FY 2016

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 (I) who are 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 (II) 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)(i)(I) of the Act further indicates that the percent of

individuals under 65 without insurance in 2013 must be the percent of such individuals who are 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). The Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. It was passed in the House of Representatives on March 21, 2010, and by the Senate on March 25, 2010. Because the House of Representatives was the first House to vote on the Health Care and Education Reconciliation Act of 2010 on March 21, 2010, we have determined that the most recent estimate 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 . . .'' (emphasis added) appeared in a March 20, 2010 letter from the director of the CBO to the Speaker of the House. Therefore, we believe that only the estimates in this March 20, 2010 letter meet the statutory requirement under section 1886(r)(2)(B)(i)(I) of the Act. (To view the March 20, 2010 letter, we refer readers to the Web site at: *http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf*.)

In its March 20, 2010 letter to the Speaker of the House of Representatives, the CBO provided two estimates of the ''post-policy uninsured population.'' The first estimate is of the ''Insured Share of the Nonelderly Population Including All Residents'' (82 percent) and the second estimate is of the ''Insured Share of the Nonelderly Population Excluding Unauthorized Immigrants'' (83 percent). Starting in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50631), we used the first estimate that includes all residents, including unauthorized immigrants. We stated that we believe this estimate is most consistent with the statute, which requires us to measure ''the percent of individuals under the age of 65 who are uninsured'' and provides no exclusions except for individuals over the age of 65. In addition, we stated that we believe that this estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than the estimate that reflects only legal residents. The March 20, 2010 CBO letter reports these figures as the estimated percentage of individuals with insurance. However, because section 1886(r)(2)(B)(i) of the Act requires that we compare the percent of individuals who are uninsured in the applicable year with the percent of individuals who were uninsured in 2013, in the FY 2014 and FY 2015 IPPS/LTCH PPS final rules (78 FR 50631 and 79 FR 50014), we used the CBO insurance rate figure and subtracted that amount from 100 percent (that is, the total population without regard to insurance status) to estimate the 2013 baseline percent of individuals without insurance. Therefore, for FYs 2014 through 2017, per statute, our estimate of the uninsurance percentage for 2013 is 18 percent.

Section 1886(r)(2)(B)(i) of the Act requires that we compare the baseline uninsurance rate to the percent of such individuals who are uninsured in the most recent period for which data are available. In the FY 2014 and FY 2015 IPPS/LTCH PPS final rules (78 FR 50634 and 79 FR 50014), we used the same data source, the most recent available CBO estimates, to calculate this percent of individuals without insurance. In response to public comments, we also agreed that we should normalize the CBO estimates, which are based on the calendar year, for the Federal fiscal years for which each calculation of Factor 2 is made (78 FR 50633).

Consistent with the data used in FY 2014 and FY 2015, in the FY 2016 IPPS/LTCH PPS proposed rule, we used the CBO's January 2015 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2014-04-ACAtables2.pdf*), normalized to the Federal fiscal year, to calculate the percent of individuals without insurance (80 FR 24486). The CBO's January 2015 estimate of individuals under the age of 65 with insurance in CY 2015 was 87 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2015 at the time of development of the FY 2016 IPPS/LTCH PPS proposed rule was 13 percent (that is, 100 percent minus 87 percent). Similarly, the CBO's January 2015 estimate of individuals under the age of 65 with insurance in CY 2016 was 89 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2016 available for the FY 2016 IPPS/LTCH PPS proposed rule was 11 percent (that is, 100 percent minus 89 percent).

The proposed calculation of Factor 2 for FY 2016 included in the FY 2016 IPPS/LTCH proposed rule was as follows:

- CY 2015 rate of insurance coverage (January 2015 CBO estimate): 87 percent.
- CY 2016 rate of insurance coverage (January 2015 CBO estimate): 89 percent.
- FY 2016 rate of insurance coverage: (87 percent * .25) + (89 percent * .75) = 88.5 percent.
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent
- Percent of individuals without insurance for FY 2016 (weighted average): 11.5 percent

$1-((0.115–0.18)/0.18) = 1-0.3611 = 0.6389$ (63.89 percent) (We note that, in the proposed rule, this calculation should have read: $1 - \left|[(0.115–0.18)/0.18)\right| = 1-0.3611 = 0.6389$ (63.89 percent).)

0.6389 (63.89 percent) − .002 (0.2 percentage points for FY 2016 under section 1886(r)(2)(B)(i) of the Act) = 0.6369 or 63.69 percent

0.6369 = Factor 2

Therefore, we proposed that Factor 2 for FY 2016 would be 63.69 percent. We indicated that our proposal for Factor 2 was subject to change if more recent CBO estimates of the insurance rate became available at the time of the preparation of the final rule. We invited public comments on our proposed calculation of Factor 2 for FY 2016.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24486), we stated that the FY 2016 Proposed Uncompensated Care Amount was $\$10,003,425,327.39 \times 0.6369 = \$6,371,181,591.01$.

Comment: A number of commenters objected to CMS' proposed calculation of Factor 2. The commenters questioned the accuracy of CBO's estimates and requested additional information on how the CBO calculates its insurance estimates, including the assumptions used in its estimates. For example, some commenters questioned the accuracy of the CBO's assumptions regarding ''unauthorized immigrants'' and provided information from other data sources, such as the Census Bureau, Department of Homeland Security Office of Immigration Statistics, and the Pew Research Center, to suggest that the total uninsured percentage in FY 2016 should be 13 percent rather than 11 percent as proposed. One commenter requested an explanation of why CBO changed its baseline formula for pre-Affordable Care Act coverage and how CBO is tracking actual insured and uninsured populations. Some commenters believed that the CBO insurance estimates do not take into

account States that have not expanded their Medicaid programs. Other commenters questioned whether CBO accounted for factors that ultimately affect the insured population, such as individuals who will disenroll from coverage due to their inability to pay premiums or insured individuals who are unable to pay for hospital services they receive due to high deductibles and coinsurance in employer-sponsored and exchange-sponsored plans.

Response: We note that, in the FY 2014 IPPS/LTCH PPS final rule, we finalized a policy to employ the most recent available CBO estimates of the rates of uninsurance in the calculation of Factor 2 for FY 2014 and subsequent years. As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50632), section 1886(r)(2)(B)(i)(I) of the Act refers to the percent of uninsured in 2013 as calculated by the Secretary based on the CBO data. Similarly, section 1886(r)(2)(B)(i)(II) of the Act immediately afterwards refers to the percent of uninsured ''in the most recent period for which data is available (as so calculated).'' The phrase ''as so calculated'' in the latter section can be reasonably interpreted to require the calculation to similarly be based on CBO estimates. Furthermore, we continue to believe that the CBO projections of insurance coverage are the most reliable and consistent basis on which to calculate Factor 2, and that it is preferable from a statistical point of view to calculate a percent change in insurance over time using a consistent data source.

We note that CBO's coverage projections for CY 2015 and CY 2016 reflect changes in the rate of uninsurance arising from participation in the health insurance exchanges, Medicaid and CHIP enrollment, and changes in employer-sponsored, nongroup, and other insurance coverage. Unauthorized immigrants who are not eligible for Medicaid and exchange coverage and low-income residents of States not participating in the Medicaid expansion are included in the uninsured population. In addition, the estimate reflects other individuals who choose to remain uninsured, despite being eligible for Medicaid or having access through an employer, the exchange, or from an insurer. Therefore, the CBO estimates do take into account some uncertainties and risks under the Affordable Care Act, including the probabilities of different outcomes of Medicaid expansions and changes in insurance coverage status over time. More detailed explanations of the methodology and assumptions used by CBO can be accessed on the CBO Web site and particularly in the Appendix of the March 2015 Updated Budget Projections: 2015–2025 (which are available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/49973-UpdatedBudgetProjections.pdf*).

Comment: Commenters requested that CMS update the Factor 2 estimates with later data, such as through an additional interim final rule or by establishing a reconciliation process that uses actual data regarding the rate of uninsurance at the time of cost report settlements. The commenters indicated that they understood that estimates must be used for interim payments, but stated that they believed more accurate numbers based on actual experience should be available for purposes of determining final payments at the time of cost report settlement. One commenter pointed out that CBO continually revises its own projected enrollment numbers for changes in insurance coverage and thus reconciliation is appropriate because otherwise providers would ''absorb the full impact of these errors.'' Another commenter objected to the view that Factor 2 should be based solely upon estimates as opposed to actual data. The commenter pointed out that the DSH statute does not use the word ''estimate'' in connection with the computation of the second prong of Factor 2. The commenter viewed the omission of the term ''estimate'' as deliberate for the period FY 2014 through FY 2017, noting that the statute employs the term ''estimate'' elsewhere, such as in the second prong of Factor 2 for FY 2018 and beyond. This commenter asserted that the statute requires that the initial estimates of the percentage of uninsured individuals for FY 2016 and FY 2017 be reconciled with actual data when those data become available.

Many commenters believed that the information shared by CMS in the FY 2016 IPPS/LTCH PPS proposed rule would be outdated and need to be revised in light of the *King* v. *Burwell* case. The commenters noted that, as of June, no decision had been issued by the Supreme Court and that an adverse ruling for the Secretary would lead to a smaller reduction in the rate of uninsurance. Some commenters provided information regarding two studies that estimated increases in the number of uninsured individuals if the Supreme Court were to set aside the subsidies in States without State-operated exchanges. The commenters stated that, based on their understanding of these studies, there could be approximately 8.2 million to 9.8 million more individuals uninsured in CY 2016 than previously estimated, which would result in a national uninsured rate of 15.1 percent to 18.3 percent. Based on this analysis, the commenters estimated that Factor 2 should be 0.8036 or 80.36 percent, much higher than the 0.6369 or 63.69 percent proposed by CMS. The commenters stated that, all else being equal, this change to Factor 2 would result in an amount to be available for uncompensated care payments of approximately $8.0 million compared to the approximately $6.4 million proposed by CMS. The commenters stated that CMS could update this estimate in the final rule or through an interim final rule. Commenters stated that updating Factor 2 for the results of the decision in *King* v. *Burwell* would reflect CMS policy to use updated data on the rate of uninsurance. One commenter requested that CMS use updated enrollment data from the exchanges to lower its estimate of the number of insured individuals for FY 2016.

Response: In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50632), we finalized a policy to employ the most recent available CBO estimates of the rate of uninsurance in the calculation of Factor 2 for FY 2014 and subsequent years, and did not adopt any policy for reconciling those estimates. In the FY 2014 IPPS/LTCH PPS final rule, we stated that we believe that employing actual data to reconcile the projections employed to determine Factor 2 would impose an unacceptable delay in the final determination of uncompensated care payments. Actual data on the rates of insurance and uninsurance do not become available until several years after the payment year, and the initial data for a year will continue to be adjusted for several years after that as further data become available. We continue to believe that determining Factor 2 prospectively by applying the best estimate of the projected level of uninsurance for the applicable fiscal year is most conducive to administrative efficiency, finality, and predictability in payments.

With respect to the commenter's concerns about language used in section 1886(r)(2)(B)(i)(II) of the Act, we acknowledge the commenter's point that the statute does not explicitly include the word ''estimate'' in describing the percent of individuals who are uninsured in the most recent period for which data are available. However, we note that the statute does describe this figure ''as so calculated.'' We continue to believe that this reference is intended to instruct the Secretary to perform the calculation in the same manner as the calculation under section 1886(r)(2)(B)(i)(I) of the Act. Section

1886(r)(2)(B)(i)(I) of the Act expressly instructs the Secretary to calculate the percent of individuals who are uninsured in 2013 ''based on the most recent *estimates* available from the Director of the Congressional Budget Office . . . .'' (Emphasis added.) Accordingly, we interpret the term ''calculated'' in section 1886(r)(2)(B)(i)(II) of the Act to mean calculated based on CBO estimates and disagree that the statute requires that we reconcile this figure with actual data.

With respect to the commenters' concerns regarding the accuracy of the Factor 2 estimate in light of the *King* v. *Burwell* case, we note that the Supreme Court's ruling in the case affirmed that individuals who purchase their health insurance on exchanges established by the Federal government are eligible for tax subsidies. As a result, we do not expect the decision to have any effect on the estimate of the percent of individuals that are uninsured in FY 2016. Moreover, we note that, because we finalized a policy in the FY 2014 IPPS/LTCH PPS final rule to use the most recent available CBO projections of insurance coverage in our calculation of Factor 2, any update to the uninsurance data used in the computation of Factor 2 must also originate from the CBO. The most recent available CBO projection of uninsurance is the March 2015 baseline available on the Web site at: *https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf*, and consistent with our policy, we are using this estimate in the calculation of Factor 2 for this FY 2016 IPPS/LTCH PPS final rule.

Comment: Some commenters requested that CMS work with Congress to take steps to mitigate the effect of the reduction in Factor 2 on the overall amount available to make uncompensated care payments for FY 2016. Several commenters requested that CMS delay the implementation of Factor 2 until all or substantially all of the States implement health insurance exchanges and until the level of Medicaid expansion is known on a State-by-State basis. The commenters expected that, once these events occur, more reliable information sources would be available to determine the reduction in the rate of uninsurance. Another commenter suggested that, at a minimum, CMS maintain the percentage of uninsured it applied in the FY 2015 calculation until a more accurate projection can be made. One commenter specifically mentioned using the documentation and coding adjustments as a model for phasing in reductions to the amount available for uncompensated care payments. Another commenter asked CMS to ensure the payment methodology does not harm access to care in rural areas.

Response: We thank the commenters for their alternative suggestions. We do not believe there is a statutory basis to delay the implementation of Factor 2 or to phase in reductions because the statute requires us to implement the uncompensated care payment methodology in its entirety for FY 2014 and each subsequent fiscal year. The statute also does not provide us with a basis to use the percentage of uninsured we applied for FY 2015 because the statute requires us to use the data on the percent of individuals who are uninsured in the most recent period for which data are available, and such data are available for FY 2016. Finally, although we understand the commenters' concerns regarding access to care in rural areas, the statute does not include any exception in the payment methodology for hospitals by geographic location or geographic classification. Therefore, hospitals in rural areas are subject to the same reductions as hospitals elsewhere in the country.

After consideration of the public comments we received, we are finalizing, as proposed, the calculation of Factor 2 for FY 2016. Using this methodology, below we discuss the resulting Factor 2 amount for FY 2016 and the total uncompensated care amount for FY 2016.

To determine Factor 2 for FY 2016, we used the CBO's March 2015 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf*). The CBO's March 2015 estimate of individuals under the age of 65 with insurance in CY 2015 is 87 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2015 is 13 percent (that is, 100 percent minus 87 percent). Similarly, the CBO's March 2015 estimate of individuals under the age of 65 with insurance in CY 2016 is 89 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2016 available for this final rule is 11 percent (that is, 100 percent minus 89 percent).

The calculation of the final Factor 2 for FY 2016, employing a weighted average of the CBO projections for CY 2015 and CY 2016, is as follows:

- CY 2015 rate of insurance coverage (March 2015 CBO estimate): 87 percent.
- CY 2016 rate of insurance coverage (March 2015 CBO estimate): 89 percent.
- FY 2016 rate of insurance coverage: (87 percent * .25) + (89 percent * .75) = 88.5 percent.
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent.
- Percent of individuals without insurance for FY 2016 (weighted average): 11.5 percent.

$1 - \left| [(0.115 - 0.18)/0.18] \right| = 1 - 0.3611 = 0.6389$ (63.89 percent)

0.6389 (63.89 percent) − .002 (0.2 percentage points for FY 2016 under section 1886(r)(2)(B)(i) of the Act) = 0.6369 or 63.69 percent

0.6369 = Factor 2

Therefore, the final Factor 2 for FY 2016 is 63.69 percent.

The FY 2016 Final Uncompensated Care Amount is: $10,058,322,396.04 × 0.6369 = $6,406,145,534.04.

FY 2016 Final Uncompensated Care Total Available.	$6,406,145,534.04

(3) Calculation of Factor 3 for FY 2016

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 (i) 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 (ii) 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, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of each 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 the Worksheet S–10 and the completeness of these data, we did not propose to use data from the Worksheet S–10 to determine the amount of uncompensated care for FY 2014, the first year this provision was in effect, or for FY 2015. We instead employed the utilization of insured low-income patients, defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in 42 CFR 412.106(b)(4) and 412.106(b)(2)(i), respectively, to determine Factor 3. We believed that these alternative data, which are currently reported on the Medicare cost report, would be a better proxy for the amount of uncompensated care provided by hospitals. We also indicated that we were expecting reporting on the Worksheet S–10 to improve over time and remained convinced that the Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24487), we stated that we believe it remains premature to propose the use of Worksheet S–10 for purposes of determining Factor 3 for FY 2016 and, therefore, proposed to continue to employ the utilization of insured low-income patients (defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in § 412.106(b)(4) and § 412.106(b)(2)(i), respectively) to determine Factor 3. We indicated that we believe that continuing to use this methodology would give hospitals more time to learn how to submit accurate and consistent data through Worksheet S–10, as well as give CMS more time to continue to work with the hospital community and others to develop the appropriate clarifications and revisions to Worksheet S–10 to ensure standardized and consistent reporting of all data elements. Accordingly, we proposed that, for FY 2016, CMS would 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 §§ 412.106(b)(2)(i) and (b)(4). We stated that we still intend to propose through future rulemaking the use of the Worksheet S–10 data for purposes of determining Factor 3. We invited public comments on this proposal to continue to use insured low-income days to determine Factor 3 for FY 2016.

Comment: Most commenters believed that the Worksheet S–10 data are not yet sufficiently consistent and reliable to be employed for purposes of determining each hospital's share of uncompensated care payments. Many commenters supported the proposal to continue employing Medicare SSI days and Medicaid days to determine Factor 3 for FY 2016.

Some commenters noted that the proxy is appropriate until the Worksheet S–10 data become more reliable and accurate for collecting uncompensated care costs. One commenter indicated that it had performed analyses exploring the relationship between uncompensated care costs and Medicaid expansion. Among other results, the commenter indicated that its analysis showed that the proportion of Medicaid volumes has increased while the proportion of self-pay and charity has decreased in States that have expanded their Medicaid programs. The commenter concluded that Medicaid and uncompensated care are now inversely related in States that have expanded their programs and stated that the validity of the insured low-income days proxy will soon be in question as newer data become available.

Commenters who continued to support use of the proxy for FY 2016 in order to allow for improved data collection on Worksheet S–10 focused on two areas: Changes to Worksheet S–10 and the process to audit Worksheet S–10. With regard to changes to Worksheet S–10, the commenters stated that the Worksheet S–10 form and instructions should be changed in order to improve consistency in reporting across providers and overall accuracy. They stated that the current instructions are imprecise and lack meaningful guidance from CMS. The commenters stated that often stakeholders provide specific recommendations for changes to Worksheet S–10 that CMS should consider, and encouraged CMS to work expeditiously with a broad range of stakeholders to improve Worksheet S–10. Many commenters provided detailed suggestions related to reporting requirements for specific lines of Worksheet S–10. Summaries that illustrate the breadth of the commenters' suggestions as they pertain, in general, to the reporting of uncompensated care, charity care, bad debt, and Medicaid costs are presented below.

- Commenters requested clarification of whether charity care charges should be reported for inpatient hospital services, outpatient hospital services, or both. They requested the ability to report these charges on separate lines and to apply separate CCRs to these separate sets of costs.
- Commenters noted that because Worksheet S–10 is derived from data reported on the Medicare cost report, charges and payments for physician services are currently excluded. However, the commenters stated that hospitals provide physician services to patients with little or no access to private physicians. They noted that safety-net hospitals in low-income communities particularly provide these services. The commenters believed that providers should be encouraged to provide these services and that one means to do so is to revise Worksheet S–10 to include reporting of uncompensated care related to employed physician services and to establish an uncompensated care cost methodology that takes these services into account.
- One commenter pointed out that it would be appropriate to add a self-pay category to Worksheet S–10 to distinguish this uninsured population from others who have some form of third party coverage.
- Commenters requested that the CCR used on Worksheet S–10 to convert charges to costs be changed so that it includes direct GME payments because

the charges include direct GME payments. To determine costs, that CCR is multiplied by the charges reported in column 8 charges, which include overhead charges that reflect direct GME. The commenters noted that the current source of the CCR on Worksheet S–10 is Worksheet C, and therefore the CCR does not include the cost of direct GME.

- Commenters requested that Worksheet S–10, which currently collects charity care costs based on dates of service, be changed to allow for the reporting of charity care costs based on the date the hospital writes off the charity care. The commenters stated that, under the current requirement, hospitals must spend significant additional time to document charity care write-offs. The commenters also stated that they do not believe the current approach is accurate because hospitals will not have identified and resolved all of their charity care accounts by the time they file their cost reports, which is no later than 5 months after the close of a hospital's fiscal year. The commenters stated that charity care determinations involve complexities, such as changes in specific patient circumstances and time involved in obtaining necessary documentation.
- Commenters noted that the current reporting instructions, particularly in PRM II, Section 4012, exclude discounts to patients from reporting as uncompensated care. They then noted that some States mandate such discounts, and that many hospitals provide discounts to any uninsured patient. In their view, these instructions could create a situation where hospitals are precluded from reporting these costs as charity when, in their view, this is uncompensated care.
- Some commenters believed that CMS should be clearer with regard to how charges related to indigent care programs are reported. The commenters believed that charges for services provided to this patient care population should not be considered uncompensated care costs. Other commenters disagreed and provided specific examples of the types of programs that should be included.
- Commenters requested that CMS define the use of presumptive eligibility tools as an acceptable method to identify and document charity care charges. The commenters believed that the current CMS practice of disallowing charity care based on the finding of presumptive eligibility tools is inappropriate because the current reporting instructions relate to when Medicare beneficiaries should be determined to be indigent and not the application of hospitals' charity care policies to other patient populations and these instructions were developed before presumptive eligibility tools were widely used by hospitals.
- Commenters believed that hospitals should not be required to report expected payments in addition to received payments for charity care accounts. The commenters noted that the difficulty is that the amounts expected from patients for whom there have been partial write-offs in accordance with a hospital's charity care policy are often not paid in full.
- Commenters believed that Worksheet S–10 understates charity care costs for patients who participate in high deductible plans. The commenters also believed that charity care for noncontracted insurance payers is overstated.
- One commenter suggested that bad debt be reported in three categories: Uninsured bad debt from charity patients; uninsured bad debt from noncharity patients; and cost-sharing bad debts. The commenter suggested that CCRs not be applied to bad debt charges related to cost-sharing. The commenter believed this disaggregation would yield data that are comparable to the charity care data reported on Worksheet S–10.
- Commenters requested that CMS be clear with regard to the time period for which bad debt expense should be reported. Specifically, the commenters asked that CMS clearly state that the instructions mean that a hospital should report bad debt expense as reflected on its financial statement. Furthermore, the commenters requested that CMS amend the cost reporting instructions to require hospitals to report amounts based on Generally Accepted Accounting Principles.
- Commenters advised requiring Medicaid DSH payments and Medicaid supplemental payment information to be reported on separate lines and to offset these payments against Medicaid costs reported on Worksheet S–10.
- Some commenters suggested that CMS capture data on the number of patients in various government programs so that any future formula based on Worksheet S–10 could provide differential weighting to hospitals based on their proportion of total inpatient and outpatient utilization by patients in these programs or payments from governmental payors such as Medicare and Medicaid. The commenters suggested collecting patient share information for non-dually eligible FFS Medicare beneficiaries, non-dually eligible Medicare Advantage beneficiaries, dual-eligible FFS beneficiaries, dual-eligible Medicare Advantage beneficiaries, and beneficiaries in the Fully Integrated Duals Advantage demonstration.

Many commenters requested that CMS consider an auditing process, ensure that its contractors administer such a process consistently, and make the instructions for such an audit public. The commenters did not believe that hospitals were purposefully reporting erroneous information on their costs reports. However, many of the commenters were concerned that unclear reporting instructions on the Worksheet S–10 would result in inconsistent and inaccurate reporting of data. They suggested that CMS look to the process used to audit and review the data used for the Medicare wage index annually. Specifically, the commenters requested that CMS develop timetables for the cut-off of submissions or changes to the data, that MACs be engaged to audit these data to ensure validity, consistency and accuracy across hospitals, and that CMS develop a public use file that would include Worksheet S–10 data to be used in that rulemaking cycle and the calculated uncompensated care payment distribution to each eligible hospital. The commenters also suggested that CMS institute a fatal edit in the cost report audit process for negative or zero uncompensated care costs. Relatedly, commenters requested that CMS provide hospitals a means to appeal adjustments to the Worksheet S–10.

Many commenters shared observations regarding concerns and anomalies they identified in data from Worksheet S–10. A number of commenters shared analysis, including analyses that looked at the proportion of hospitals that did not report bad debt expenses, that reported a higher amount for gross charges on Worksheet S–10 than Worksheet C, or reported CCRs that seemed inappropriately high (such as for all-inclusive rate facilities). In addition, one commenter questioned imputed values for CAHs. Other commenters noted that the current requirements result in negative uncompensated care values for some hospitals.

These commenters, as well as commenters who opposed the continuation of the proxy, also requested that CMS provide a tentative timeline and implementation process for when and how the Worksheet S–10 would be used for determining Medicare uncompensated care payments. Some commenters suggested that CMS delay the use Worksheet S–10 until an audit process is established, and suggested a delay of at least 4 years.

Some commenters requested a transition from using a Factor 3 based on insured low income days to a Factor 3 based on uncompensated care costs from another source such as Worksheet S–10. These commenters suggested a variety of methods for such a transition, including blending or combining the Factor 3 values, and also a variety of lengths for such a transition, such as 3 years or 10 years. Some commenters requested that CMS implement caps on redistribution, such as a maximum cap of 10 percent on any redistribution of uncompensated care payments for 5 years, in the absence of a transition. These commenters expressed concern regarding sudden destabilizing losses due a change in their uncompensated care payments, noting that providing for a transition would prevent financial shocks to hospitals and create an incentive for them to more accurately report uncompensated care on Worksheet S–10.

Some commenters suggested how CMS should define uncompensated care using information from Worksheet S–10 and additional information that they believed should be collected in order to determine uncompensated care. For example, the commenters believed that bad debts and charity care should be included in the definition of uncompensated care. Some commenters specifically indicated that they believe that CMS should treat the uncompensated portion of state or local indigent care programs as charity care. The commenters also believed that costs not covered by Medicaid payments should be included in the definition of uncompensated care because they are not compensated. The commenters also noted that this approach would improve consistency across hospitals for comparison purposes because some hospitals treat some of these costs as charity care costs based on their charity care policies. Commenters provided different views with regard to publicly funded indigent care programs. Some commenters believed that charges for services provided to these patient populations should not be included. Other commenters believed that these charges should be included and that neither private nor public grant monies should be subtracted from them.

Response: We appreciate the commenters' support for the use of data on low-income insured days as a proxy for uncompensated care in calculating uncompensated care payments until Worksheet S–10 data become more reliable. We expect reporting on Worksheet S–10 to improve over time, both in accuracy and consistency, particularly in the area of charity care, which is already being used and audited for payment determinations related to the EHR Incentive Program. Since the publication of the FY 2014 IPPS/LTCH PPS final rule, we have continued to evaluate and assess the comments we have received from stakeholders about Worksheet S–10 as well as to consider what changes might need to be made to the instructions to improve the data submitted by hospitals. Although we have not decided upon revisions to the Worksheet S–10 instructions at this time, we remain committed to making improvements to Worksheet S–10 if we find they are warranted. We appreciate the specific recommendations from commenters for changing the Worksheet S–10 form and instructions and will take them into consideration as we continue to evaluate reporting on Worksheet S–10.

We have noted that we expect to proceed with a proposal to use data on the Worksheet S–10 to determine uncompensated care costs in the future and also have indicated that we will take steps such as revising and clarifying cost report instructions, as appropriate. We have stated that it is our intention to propose introducing the use of the Worksheet S–10 data for purposes of determining Factor 3 within a reasonable amount of time. At this time, we are considering a possible timeline for using Worksheet S–10 data to calculate Factor 3, and we intend to discuss this further in the FY 2017 IPPS proposed rule, which is typically released in April of the preceding fiscal year.

Comment: Several commenters objected to the proposal to calculate Factor 3 based on a hospital's share of total Medicaid days and Medicare SSI days as a proxy for measuring a hospital's share of uncompensated care. Many of these commenters believed that continued use of the proxy rewards providers in States where Medicaid has expanded. The commenters asserted that CMS should not finalize its proposal to use low-income insured days as a proxy for uncompensated care costs as proposed and instead supported the use of Worksheet S–10 data to determine uncompensated care costs for FY 2016. In particular, MedPAC disagreed with CMS' statement that the data on utilization for insured low-income patients can serve as a reasonable proxy for the treatment costs of uninsured patients. MedPAC specifically cited its 2007 analysis of data from the GAO and data from the American Hospital Association (AHA), which suggests that Medicaid days and low-income Medicare days are not a good proxy for uncompensated care costs. MedPAC also provided additional analyses that found that current Worksheet S–10 data, compared to Medicaid/Medicare SSI days, are a better proxy for predicting audited uncompensated care costs. Specifically, MedPAC included an analysis testing whether data from the Worksheet S–10 or Medicaid and Medicare SSI days are a better indicator of costs associated with caring for the uninsured. The analysis compared 2011 data from Worksheet S–10 and 2011 Medicaid and Medicare SSI days with 2009 audited data obtained from the Medicaid and CHIP Payment and Access Commission (MACPAC). The analysis found that the correlation between audited uncompensated care data and data from the Worksheet S–10 was over 0.80, whereas the correlation between audited uncompensated care data and Medicaid and Medicare SSI days was only about 0.50. Moreover, the analysis found that the 2011 S–10 data explained over 60 percent of the variance in audited uncompensated care costs whereas Medicaid days and Medicare SSI days only explain about 25 percent of the variance. Therefore, MedPAC believed that using Medicare SSI/Medicaid days as a proxy for uncompensated care does not appropriately target hospitals with the highest burden of uncompensated care costs and supported Worksheet S–10 in the Medicare cost report as an appropriate measure of uncompensated care that could begin to replace the reliance on Medicaid and Medicare SSI day shares. In response to concerns about whether the quality of the data reported on Worksheet S–10 is adequate for use in distributing uncompensated care payments, MedPAC argued that these data are already better than using Medicaid and Medicare SSI days as a proxy for uncompensated care costs, and that the data on Worksheet S–10 will improve over time as the data are actually used in making payments.

Response: As we stated in the FY 2014 and FY 2015 IPPS/LTCH PPS final rules, we believe that data on utilization for insured low-income patients can be a reasonable proxy for the treatment costs of uninsured patients. Moreover, due to the concerns that continue to be expressed by commenters regarding the accuracy and consistency of the data reported on the Worksheet S–10, we continue to believe that Medicaid and Medicare SSI days remain a better proxy at this time for the amount of uncompensated care provided by hospitals. However, we remain convinced that Worksheet S–10 can ultimately serve as an appropriate source of more direct data regarding

uncompensated care costs for purposes of determining Factor 3. Worksheet S–10 was developed specifically to collect information on uncompensated care costs in response to interest by MedPAC and other stakeholders regarding the topic (for example, MedPAC's March 2007 Report to Congress), and it is not unreasonable to expect information on the cost report to be used for payment purposes. We are continuing to review available data on the suitability of the Worksheet S–10 data, and are encouraged by MedPAC's analysis showing a high correlation between Medicaid audited uncompensated care data and data reported on Worksheet S–10. We also are refining our benchmarking analyses in order to compare available Worksheet S–10 data to other data sources on uncompensated care, such as uncompensated care costs reported to the Internal Revenue Service on Form 990 by not-for-profit hospitals.

As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50639), in using Medicaid and Medicare SSI days as a proxy for uncompensated care, we recognize 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. Regardless, for the reasons discussed above, we believe that data on insured low-income days remain the best proxy for uncompensated care costs currently available to determine Factor 3.

Comment: One commenter believed that the current methodology utilizing low-income insured days as a proxy for uncompensated care does not differentiate between the types of inpatient days or consider the degree of acuity for patients with advanced medical conditions. The commenter suggested that CMS apply a wage and case-mix adjustment to the Medicaid and Medicare SSI days using the hospital area wage index and hospital-specific case-mix index. The commenter believed that this adjustment was appropriate in order to measure cost variation among hospitals.

Response: We appreciate the commenter's expression of the need to wage and case-mix adjust the Medicaid and SSI days, but we continue to believe it is not appropriate to apply a wage index or case-mix adjustment to low-income days to calculate Factor 3 for FY 2016. Although wage index information is readily available, for the reasons discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50639) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50017), we continue to believe that it is not an accurate measure of the intensity of uncompensated care costs and would not serve as an appropriate basis for making adjustments to Factor 3. As for case-mix information, as stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50636), these data continue to be unavailable to us.

Comment: One commenter requested that CMS consider the possibility of using a proxy for SSI days in the calculation of Factor 3 and for other purposes related to DSH for Puerto Rico. The commenter noted that U.S. citizens residing in Puerto Rico are not entitled to SSI benefits, and that the reliance upon SSI enrollment in calculating Factor 3 results in uncompensated care payments that are unintentionally and unfairly lower for providers in Puerto Rico.

Response: As discussed earlier, we are currently using the utilization of insured low-income patients, defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients, as a proxy to estimate a hospital's uncompensated care. When we adopted this methodology for distributing uncompensated care payments for FY 2014, we estimated Puerto Rico hospitals would receive a 41.3 percent increase in Medicare DSH and uncompensated care payments (78 FR 51009). While this increase was moderated with a reduction of 7.7 percent in FY 2015 (79 FR 50412), the methodology used to determine uncompensated care payments significantly benefitted Puerto Rico hospitals relative to the methodology used to determine DSH payments under section 1886(d)(5)(F) of the Act. Further, as previously discussed, it is our intention to propose introducing the use of Worksheet S–10 of the Medicare cost report for purposes of distributing the uncompensated care payments within a reasonable amount of time. We note that eligibility for SSI days will not be an issue in determining uncompensated care payments after the move to Worksheet S–10 because Medicare SSI days will no longer be used in the distribution methodology. We have encouraged Puerto Rico hospitals to report uncompensated care costs on Worksheet S–10 of the Medicare cost report completely and accurately so that when we transition to the use of the Worksheet S–10, they can continue to receive the share of the uncompensated care payments to which they are entitled. If Puerto Rico hospitals do not properly report uncompensated care costs on Worksheet S–10, they risk a substantial reduction in future payments.

In the interim, until we are ready move to use of Worksheet S–10 for distributing the uncompensated care payments, we acknowledge that use of SSI Medicare inpatient days in the distribution of uncompensated care payments may disadvantage Puerto Rico hospitals. However, as there was no proposal to modify the methodology for distributing uncompensated care payments to Puerto Rico hospitals in the FY 2016 IPPS/LTCH PPS proposed rule, we do not believe that there would be logical outgrowth to adopt such a change in this FY 2016 IPPS/LTCH PPS final rule. Any change to the proxy used to determine uncompensated care for Puerto Rico hospitals would need to be adopted through notice-and-comment rulemaking. We plan to address this issue for inclusion in the FY 2017 IPPS/LTCH PPS proposed rule if we also propose to continue using inpatient days of Medicare SSI patients as a proxy for uncompensated care in FY 2017.

Comment: Some commenters asserted that the FY 2016 IPPS/LTCH PPS proposed rule failed to address the impact of *Allina* v. *Sebelius* on the Medicare DSH and uncompensated care formulas. The commenters asserted that, with regard to Medicaid and Medicare SSI days used in the calculation of Factor 3, the FY 2011/2012 cost reports do not appropriately reflect dual eligible MA days in conjunction with the court's ruling in *Allina.* In addition, one commenter stated that the 2013 SSI ratios, which were released by CMS in May 2015, appear to include MA days, which is inconsistent with the court's ruling in the *Allina* case.

Response: We do not believe the *Allina* decision has any bearing on our estimate of Factor 3 for FY 2016. The decision in *Allina* did not address the issue of how patient days should be counted for purposes of estimating uncompensated care. Moreover, section 1886(r)(2)(C) of the Act provides discretion for the Secretary to determine how to estimate uncompensated care costs. We continue to believe that, for purposes of determining uncompensated care payments, Medicare SSI days should include both MA and FFS SSI days.

After consideration of the public comments we received, we continue to believe that using low-income insured days as a proxy for uncompensated care costs provides a reasonable basis to determine Factor 3 as we work to improve Worksheet S–10 to accurately and consistently capture uncompensated care costs. Accordingly, in this final rule, we are finalizing for FY 2016 the policy that we originally adopted in the FY 2014 IPPS/LTCH PPS

final rule, of employing the utilization of insured low-income patients, defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in 42 CFR 412.106(b)(4) and 412.106(b)(2)(i), respectively, to determine Factor 3 for FY 2016. Details on the calculation of Factor 3 for FY 2016 follow.

As we did for the FY 2014 and FY 2015 IPPS/LTCH PPS proposed rules, for the FY 2016 IPPS/LTCH PPS proposed rule, we published on the CMS Web site a table listing Factor 3 for all hospitals that we estimated would receive empirically justified Medicare DSH payments in FY 2016 (that is, hospitals that we projected 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 DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. Hospitals had 60 days from the date of public display of the FY 2016 IPPS/LTCH PPS proposed rule to review these tables and notify CMS in writing of a change in a hospital's subsection (d) hospital status, such as if a hospital closed or converted to a CAH.

After the publication of this FY 2016 IPPS/LTCH final rule, hospitals will have until August 31, 2015, to review and submit comments on the accuracy of these tables. Comments can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2015, and any changes to Factor 3 will be posted on the CMS Web site prior to October 1, 2015.

The statute 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 2015 IPPS/LTCH PPS final rule (79 FR 50018), we finalized a policy to use the most recently available full year of Medicare cost report data for determining Medicaid days and the most recently available SSI ratios. This is consistent with the policy we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638) of calculating the numerator and the denominator of Factor 3 for hospitals based on the most recently available full year of Medicare cost report data (including the most recently available data that may be used to update the SSI ratios) with respect to a Federal fiscal year. In other words, we used data from the most recently available full year cost report for the Medicaid days, the most recent cost report data submitted to CMS by IHS hospitals, and the most recently available SSI ratios (that is, latest available SSI ratios before the beginning of the Federal fiscal year) for the Medicare SSI days. Therefore, to estimate Factor 3 for FY 2015, we used data from the most recently available full year cost report and the most recent cost report data submitted to CMS by IHS hospitals for the Medicaid days and the most recently available SSI ratios, which for FY 2015 were data obtained from the 2011/2012 cost reports and the 2010 cost report data submitted by IHS hospitals for the Medicaid days, and the FY 2012 SSI ratios for the Medicare SSI days.

Since the publication of the FY 2015 IPPS/LTCH PPS final rule, we have been informed by the hospital community that they are experiencing difficulties with submitting accurate data for Medicaid days within the timeframes noted in the Provider Reimbursement Manual, Part 2, for a variety of reasons, such as their ability to receive eligibility data from State Medicaid agencies. (As outlined in Section 104, Chapter 1, of the Provider Reimbursement Manual, Part 2, a hospital generally has 5 months after the close of its cost reporting period to file its cost report.) In addition, we have been informed that there is variation in the ability of hospitals and MACs, respectively, to submit and accept amended cost report data in time for the computation of Factor 3. While we continue to believe that it is important to use data that are as recent as possible, we recognize that, from time to time, the balance between recency and accuracy may require refinement. In the case of Factor 3, because we make prospective determinations of the uncompensated care payment without reconciliation, we believe that it would increase the accuracy of the data used to determine Factor 3, and accordingly, each eligible hospital's allocation of the overall uncompensated care amount, if we provided hospitals with more time to submit these data and MACs with more time to consider these submitted data before they are used in the computation of Factor 3. As we described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50018), it is not possible for us to wait for a later database update of the cost report data to calculate the final Factor 3 amount for the final rule because this could cause delay in the publication of the final rule. Therefore, we are unable to provide hospitals additional time to submit supplemental data, or for their MACs to consider and accept those data as applicable and appropriate. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24488), we noted that one alternative would be to use slightly older data within the most recent extract of the hospital cost report data in the HCRIS database. We stated that we believe this would allow hospitals more time to submit data and MACs more time to consider and accept such data as applicable and appropriate.

Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24488), for the computation of Factor 3 for FY 2016, we proposed to hold constant the cost report years used to calculate Factor 3 and to use data from the 12-month 2012 or 2011 cost reports and, in the case of IHS hospitals, the 2012 cost report data submitted to CMS by IHS hospitals. However, because a more recent HCRIS database was available at the time of the development of the FY 2016 proposed rule, we proposed that we would continue to use the most recent HCRIS database extract available to us at the time of the annual rulemaking cycle. We noted that, as in prior years, if the more recent of the two cost reporting periods does not reflect data for a 12-month period, we would use data from the earlier of the two periods so long as that earlier period reflects data for a period of 12 months. If neither of the two periods reflects 12 months, we would use the period that reflects a longer amount of time. We proposed to codify this change for FY 2016 by amending

the regulations at § 412.106(g)(1)(iii)(C). We invited public comments on this proposal, which we describe more fully below.

For the FY 2015 IPPS/LTCH PPS final rule, we used the more recent of the full year 2012 or full year 2011 data from the March 2014 update of the hospital cost report data in the HCRIS database and 2010 cost report data submitted to CMS by IHS hospitals as of March 2014 to obtain the Medicaid days to calculate Factor 3. In addition, we used the FY 2012 SSI ratios published on the following CMS Web site to calculate Factor 3: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Dsh.html*. In contrast, under our proposal for FY 2016, we indicated we would use the more recent of the full year 2012 or full year 2011 data from the March 2015 update of the hospital cost report data in the HCRIS database and the 2012 cost report data submitted to CMS by IHS hospitals to obtain the Medicaid days to calculate Factor 3. In addition, to calculate Factor 3 for FY 2016, we anticipated that, under our proposal, we would use the FY 2013 SSI ratios that we expected to be published on the CMS Web site but were not yet available before the public display of the proposed rule. For illustration purposes, in Table 18 associated with the FY 2016 proposed rule (which is available via the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Proposed-Rule-Home-Page-Items/FY2016-IPPS-Proposed-Rule-Tables.html*), we computed Factor 3 using the more recent of the full year 2012 or 2011 data from the December 2014 update of the hospital cost report data in the HCRIS database to obtain the Medicaid days and the FY 2012 SSI ratios published on the CMS Web site. We anticipated using the more recent of the full year 2012 or 2011 data from the March 2015 update of the hospital cost report data in the HCRIS database to obtain the Medicaid days and the FY 2013 SSI ratios to determine the final Factor 3 for FY 2016.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24488), we stated that for subsequent years, if we propose and finalize a policy of using insured low-income days in computing Factor 3, we intend to continue to use the most recent HCRIS database extract at the time of the annual rulemaking cycle, and to use the subsequent year of cost reports, as applicable, using the methodology described above (that is, to advance the 12-month cost reports by 1 year). We noted that, starting with the 2013 cost reports, data for IHS hospitals will be included in the HCRIS. Therefore, if an IHS hospital has a 12-month 2013 cost reporting period in the HCRIS database, we will not need to use the 2012 data separately submitted to CMS by the IHS hospital. For example, if we finalize for FY 2017, a policy under which Factor 3 is determined on the basis of insured low-income days, this approach would result in the use of the more recent of the 12-month 2013 or 2012 cost reports in the most recent HCRIS database extract available at the time of rulemaking. In addition, for any subsequent years in which we finalize a policy to use insured low-income days to compute Factor 3, our intention would be to continue to use the most recently available SSI ratio data to calculate Factor 3 at the time of annual rulemaking. As we indicated in the FY 2016 IPPS/LTCH PPS proposed rule, we believe that it is appropriate to state our intentions regarding the specific data we would use in the event Factor 3 is determined on the basis of low-income insured days for subsequent years to provide hospitals with as much guidance as possible so they may best consider how and when to submit cost report information in the future. We note that we will make proposals with regard to our methodology for calculating Factor 3 for subsequent years through notice-and-comment rulemaking.

Comment: Several commenters supported the proposal to use more recent of the full year 2012 or 2011 data from the March 2015 update of the hospital cost report data in the HCRIS database to obtain the Medicaid days and the FY 2013 SSI ratios to determine the final Factor 3 for FY 2016. Other commenters stated that they did not oppose the proposal.

Response: We appreciate the commenters' support for or lack of opposition to this proposal.

Comment: Several commenters questioned the data used to calculate the hospitals' Factor 3 and requested clarifications on various aspects of the proposed policy. For example, several commenters stated that their Medicaid days were understated, and other commenters stated that their Medicaid days were based on a 6-month cost report and they should be based on a 12-month cost report either by combining cost reports or annualizing the data. Several commenters requested that CMS clarify whether the 12-month 2012 cost report would have to fall within the Federal fiscal year, or if CMS intends to use the full year cost report from previous years if there are no full year cost reports during the period. One commenter suggested that, for a new hospital for which the applicable historical cost reporting data represent less than 12 months, CMS use the full 12-month cost reporting data that are closest to the cost reporting period selected for determining Factor 3 in the FY 2016 IPPS/LTCH PPS final rule even if these cost reporting data are more recent than the selected period. The commenter also recommended, as an alternative, that CMS allow a new hospital to settle its uncompensated care payment on its filed cost report for the applicable fiscal year until the cost reporting period data that are applicable for computing Factor 3 include a full 12-month cost reporting period. One commenter asked for clarification on which SSI ratios will be used to settle the FY 2015 and FY 2016 cost reports, as well as which SSI ratios will be used for what purpose. A number of commenters provided information regarding their Medicaid days and requested changes based on that information.

Response: We appreciate the commenters raising these data concerns and areas of needed clarification. We are finalizing our proposal to calculate Factor 3 using SSI days from the FY 2013 SSI ratios and Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals and the more recent of hospital-specific full year 2012 cost reports (unless that cost report is unavailable or reflects less than a full 12-month year, in which case we will use the cost report from 2012 or 2011 that is closest to being a full 12-month cost report) from the March 2015 update of the hospital cost report data in the HCRIS database. We also are finalizing our proposed revisions to the regulation at § 412.106(g)(1)(iii)(C), which codifies the cost reporting periods selected for purposes of determining Factor 3 of the uncompensated care payment methodology for FY 2016. We note that since we issued the FY 2016 IPPS/LTCH PPS proposed rule, the FY 2013 SSI ratios have become available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Dsh.html*. We also clarify that the 12-month cost report does not need to coincide with the Federal fiscal year.

With regard to the comments from hospitals that found their Factor 3 was calculated using a cost report that was less than 12 months, we are finalizing our proposal to use the 2012 cost report, unless that cost report is unavailable or reflects less than a full 12-month year. In the event the 2012 cost report is for less than 12 months, we will use the cost report from 2012 or 2011 that is

closest to being a full 12-month cost report. In the case where a less than 12-month cost report is used to calculate a hospital's Factor 3, this would indicate that both the 2012 and 2011 cost reports were less than 12 months. In such a case, we will use the longer of the two cost reports to calculate a hospital's Factor 3. We note that section 1886(r)(2)(C) of the Act specifies that Factor 3 is equal to the percent that represents the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data divided by the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment for such period (as so estimated). In implementing this provision, as we did through rulemaking in the FY 2014 IPPS/LTCH PPS final rule, we noted that we believed it was appropriate to first select the period—in that case, the period for which we had the most recently available data—and then to select the data from a cost report that aligns best with that period. Based upon our experience with implementing the provision for FY 2014 and FY 2015, we have determined that it is more appropriate to use the most recent extract of hospital cost report data for a slightly earlier period in order to give hospitals more time to submit data and MACs more time to consider and accept that data. As we have discussed, we believe this policy will improve the accuracy of the data used to calculate Factor 3. However, we acknowledge that the situations presented by commenters, where a hospital remains in operation in both Federal fiscal years for which we analyze cost report data but submits cost reports for both Federal fiscal years that reflect substantially less than a full year of data, pose unique challenges in the context of estimating Factor 3. We did not make a proposal to annualize or combine cost reports to calculate Factor 3. As a result, this is an issue that we intend to consider further and may address in future rulemaking.

As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643), for new hospitals, which for Medicare DSH purposes include hospitals with a CCN established after 2012, we do not have data currently available to determine if the new hospital is eligible for empirically justified Medicare DSH payments and, therefore, eligible to receive an uncompensated care payment for FY 2016, nor do we have the data necessary to calculate a Factor 3 amount. Accordingly, we will treat new hospitals in the same manner as hospitals that are not found to be eligible to receive empirically justified Medicare DSH payments based upon the most recent available cost report from 2012 or 2011, such that the hospital may 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 2016 cost report, the hospital also will receive an uncompensated care payment based on the sum of Medicaid days and Medicare SSI days reported on its FY 2016 cost report.

In response to the commenters' concerns about which SSI ratios will be used for what purpose, we note that, consistent with our methodology in FY 2014 and FY 2015, the most recently available SSI ratios, in conjunction with the Medicaid fraction listed in the most recent update of the Provider Specific File, are used to identify which hospitals are projected to receive empirically justified DSH payments for FY 2016, and thus are eligible to receive interim uncompensated care payments for FY 2016. For this FY 2016 IPPS/LTCH PPS final rule, the 2013 SSI ratios are the most recently available SSI ratios and the March 2015 update is the most recent update of the Provider Specific File. The final determination as to whether a hospital is eligible to receive empirically justified DSH payments and therefore eligible to receive an uncompensated care payment is made at cost report settlement using the SSI ratio and Medicaid fraction reported on the provider's FY 2016 cost report. Therefore, for FY 2016, the 2013 SSI ratios are used to project eligibility to receive interim empirically justified DSH payments and interim uncompensated care payments, and the 2016 SSI ratios are used to determine, at cost report settlement, whether the hospital is ultimately eligible for empirically justified DSH payments and the uncompensated care payment. Furthermore, as stated elsewhere in this final rule, the SSI days from the 2013 SSI ratios are used in computing Factor 3. The calculation of Factor 3 in this final rule is a final determination that is not subject to review and will not be revised at cost report settlement to reflect updated information regarding the eligibility of individual hospitals for empirically justified DSH payments and uncompensated care payments.

Comment: Several commenters requested additional time after the publication of the final rule to review the data used to calculate Factor 3 and submit corrections. Some commenters asked questions regarding whether or not Medicaid days from more recent cost reports than the cost reporting periods we proposed to use could be included for their hospitals in determining Factor 3 for FY 2016. Some of these commenters included specific information and copies of documentation related to these days.

Response: We thank the commenters for their submissions. Regarding the data used to calculate Factor 3, we believe that the SSI days from the FY 2013 SSI ratios and Medicaid days from the more recent of hospitals' 2012 or 2011 cost report (that encompasses a period closest to 12 months) from the March 2015 HCRIS extract, as well as Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals, should be used to determine Factor 3. As we stated above, we believe using 2011/2012 cost report data will allow hospitals more time to submit their cost report data and MACs more time to consider and accept such data as applicable and appropriate, thus balancing recency and accuracy. We cannot allow for further updates and revisions to the data used to determine Factor 3 because they would cause an unacceptable delay in the publication of this final rule and prevent changes and updates to payments under the IPPS from taking effect on October 1, the first day of the fiscal year. Furthermore, the statute provides the Secretary with the authority and discretion to estimate the amount of uncompensated care for a hospital and also provides the Secretary with the authority and discretion to select the time period for which this uncompensated care amount is estimated.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24488), we proposed 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 for FY 2016 and subsequent fiscal years. In order to confirm mergers and ensure the accuracy of the data used to determine each merged hospital's uncompensated care payment, we stated that we would publish a table on the CMS Web site, in conjunction with the issuance of each Federal fiscal year's IPPS/LTCH PPS proposed and final rules, that contains 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 each year's IPPS/LTCH PPS proposed rule to review these tables and notify CMS in writing of any

inaccuracies. After the publication of the IPPS/LTCH PPS final rule, hospitals will have until August 31 of that year (for FY 2016, the deadline is August 31, 2015) to review and submit comments on the accuracy of the table for the applicable fiscal year. Comments can be submitted to our inbox at *Section3133DSH@cms.hhs.gov* through August 31, and any changes to Factor 3 will be posted on the CMS Web site prior to the start of the applicable fiscal year on October 1. We invited public comments on our proposal to continue these policies concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers, as described above.

Comment: Some commenters provided detailed information regarding specific merger situations involving their hospitals and requested that CMS consider these mergers in determining Factor 3 for FY 2016. One commenter expressed concern that if a hospital is not identified as having undergone a merger prior to the public display of the final rule, a recalculation would be performed on the surviving hospital's Factor 3 at the end of the applicable fiscal year in which the merger has taken place. The commenter was concerned that this process may result in an extended delay before a hospital's uncompensated care payment is corrected and may result in understated interim uncompensated care payments. The commenter recommended an alternate approach for the recalculation of a hospital's Factor 3 that utilizes the tentative settlement process currently used by the MACs for the purpose of updating the hospital's payment rate prior to final settlement.

Response: We appreciate the commenters' input. As in FY 2015, we published a table on the CMS Web site in conjunction with the issuance of the proposed rule containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. The affected hospitals had the opportunity to comment during the public comment period on the accuracy of this information. We have updated our list of mergers based on information submitted by the MACs as of June 2015. In addition, we have reviewed the commenters' submissions of mergers not previously identified in the proposed rule and have updated our list accordingly.

While we continue to believe that recalculation of a surviving hospital's Factor 3 at cost report settlement is the most conducive to administrative efficiency and predictability for both providers and MACs, we may explore the possibility of an alternative approach in which recalculation occurs during the tentative settlement process in future notice-and-comment rulemaking. In addition, we remind the commenters that, in the event that a merger is not identified by the MACs, we allow opportunity for comment on the accuracy of the mergers that we have identified during the comment period for the proposed rule and after the publication of the final rule. Hospitals have until August 31, 2015 to review and submit comments on the accuracy of the list of mergers that we have identified in this final rule.

E. Hospital Readmissions Reduction Program: Changes for FY 2016 Through FY 2017 (§§ 412.150 through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added a new section 1886(q) to the Act. Section 1886(q) of the Act establishes the ''Hospital Readmissions Reduction Program,'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those applicable hospitals may be reduced to account for certain excess readmissions.

Section 1886(q)(1) of the Act sets forth the methodology by which payments to ''applicable hospitals'' will be adjusted to account for excess readmissions. In accordance with section 1886(q)(1) of the Act, payments for discharges from an ''applicable hospital'' will be an amount equal to the product of the ''base operating DRG payment amount'' and the adjustment factor for the hospital for the fiscal year. That is, ''base operating DRG payments'' are reduced by a hospital-specific adjustment factor that accounts for the hospital's excess readmissions. Section 1886(q)(2) of the Act defines the base operating DRG payment amount as the payment amount that would otherwise be made under section 1886(d) of the Act (determined without regard to section 1886(o) of the Act [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of section 1886(d) of the Act. Paragraphs (5)(A), (5)(B), (5)(F), and (12) of section 1886(d) of the Act refer to outlier payments, IME payments, DSH adjustment payments, and add-on payments for low-volume hospitals, respectively.

Furthermore, section 1886(q)(2)(B) of the Act specifies special rules for defining the payment amount that would otherwise be made under section 1886(d) of the Act for certain hospitals, including policies for SCHs and for MDHs for FY 2013. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374), we finalized policies to implement the statutory provisions related to the definition of ''base operating DRG payment amount'' with respect to those hospitals.

Section 1886(q)(3)(A) of the Act defines the ''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. 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. Section 1886(q)(3)(C) of the Act establishes the floor adjustment factor, which is set at 0.97 for FY 2015 and subsequent fiscal years.

Section 1886(q)(4) of the Act defines the terms ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' for an applicable hospital for the applicable period. The term ''aggregate payments for excess readmissions'' is defined in section 1886(q)(4)(A) of the Act as the sum, for applicable conditions of the product, for each applicable condition, of (i) The base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1. The ''excess readmissions ratio'' is a hospital-specific ratio based on each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmissions ratio as the ratio of actual-over-expected readmissions; specifically, the ratio of ''risk-adjusted readmissions based on actual readmissions'' for an applicable hospital for each applicable condition, to the ''risk-adjusted expected readmissions'' for the applicable hospital for the applicable condition.

Section 1886(q)(5) of the Act provides definitions of ''applicable condition,'' ''expansion of applicable conditions,'' ''applicable hospital,'' ''applicable period,'' and ''readmission.'' The term

''applicable condition'' (which is addressed in detail in section IV.C.3.a. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51665 through 51666)) is defined as a condition or procedure selected by the Secretary among conditions and procedures for which: (i) Readmissions represent conditions or procedures that are high volume or high expenditures and (ii) measures of such readmissions have been endorsed by the entity with a contract under section 1890(a) of the Act and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital). Section 1886(q)(5)(B) of the Act also requires the Secretary, beginning in FY 2015, to the extent practicable, to expand the applicable conditions beyond the three conditions for which measures have been endorsed to the additional four conditions that have been identified by the MedPAC in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary.

Section 1886(q)(5)(C) of the Act defines ''applicable hospital,'' that is, a hospital subject to the Hospital Readmissions Reduction Program, as a subsection (d) hospital or a hospital that is paid under section 1814(b)(3) of the Act, as the case may be. The term ''applicable period,'' as defined under section 1886(q)(5)(D) of the Act, means, with respect to a fiscal year, such period as the Secretary shall specify. As explained in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), the ''applicable period'' is the period during which data are collected in order to calculate various ratios and payment adjustments under the Hospital Readmissions Reduction Program.

Section 1886(q)(6) of the Act sets forth the public reporting requirements for hospital-specific readmission rates. Section 1886(q)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(q) of the Act. Finally, section 1886(q)(8) of the Act requires the Secretary to collect data on readmission rates for *all* hospital inpatients (not just Medicare patients) for a broad range of both subsection (d) and nonsubsection (d) hospitals in order to calculate the hospital-specific readmission rates for all such hospital inpatients and to publicly report these ''all-patient'' readmission rates.

2. Regulatory Background

The payment adjustment factor set forth in section 1886(q) of the Act did not apply to discharges until FY 2013. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed the issues of the selection of readmission measures and the calculation of the excess readmissions ratio, which will be used, in part, to calculate the readmissions adjustment factor. Specifically, in that final rule, we finalized policies that relate to the portions of section 1886(q) of the Act that address the selection of and measures for the applicable conditions, the definitions of ''readmission'' and ''applicable period,'' and the methodology for calculating the excess readmissions ratio. We also established policies with respect to measures for readmissions for the applicable conditions and our methodology for calculating the excess readmissions ratio.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401), we finalized policies that relate to the portions of section 1886(q) of the Act that address the calculation of the hospital readmissions payment adjustment factor and the process by which hospitals can review and correct their data. Specifically, in that final rule, we addressed the base operating DRG payment amount, aggregate payments for excess readmissions and aggregate payments for all discharges, the adjustment factor, applicable hospital, limitations on review, and reporting of hospital-specific information, including the process for hospitals to review readmission information and submit corrections. We also established a new Subpart I under 42 CFR part 412 (§§ 412.150 through 412.154) to codify rules for implementing the Hospital Readmissions Reduction Program.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676), we finalized our policies that relate to refinement of the readmissions measures and related methodology for the current applicable conditions, expansion of the ''applicable conditions'' for FY 2015 and subsequent fiscal years, and clarification of the process for reporting hospital-specific information, including the opportunity to review and submit corrections. We also established policies related to the calculation of the adjustment factor for FY 2014.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048), we made refinements to the readmissions measures and related methodology for applicable conditions for FY 2015 and subsequent fiscal years, expanded the ''applicable conditions'' for FY 2017 and subsequent fiscal years, discussed the maintenance of technical specifications for quality measures, and described a waiver from the Hospital Readmissions Reduction Program for hospitals formerly paid under section 1814(b)(3) of the Act (§ 412.154(d)). We also specified the applicable period for FY 2015 and made changes to the calculation of the aggregate payments for excess readmissions to include two additional applicable conditions for the FY 2015 payment determination.

3. Overview of Policies for the FY 2016 and FY 2017 Hospital Readmissions Reduction Program

In this final rule, for the FY 2016 Hospital Readmissions Reduction Program, we are—

- Specifying the adjustment factor floor for FY 2016 (section IV.E.6. of the preamble of this final rule);
- Specifying the applicable period for FY 2016 (section IV.E.7. of the preamble of this final rule);
- Specifying the calculation of aggregate payments for excess readmissions for FY 2016 (section IV.E.8. of the preamble of this final rule); and
- Adopting an extraordinary circumstance exception policy to address hospitals that experience a disaster or other extraordinary circumstance beginning in FY 2016 and for subsequent years (section IV.E.9. of the preamble of this final rule).

In addition, in this final rule, for the FY 2017 Hospital Readmissions Reduction Program, we are making a refinement to the pneumonia readmissions measure, which would expand the measure cohort, for the FY 2017 payment determination and subsequent years (section IV.E.4. of the preamble of this final rule).

We note that, during the comment period for the FY 2016 IPPS/LTCH PPS proposed rule, we received public comments that were not related to our specific proposals for the Hospital Readmissions Reduction Program and therefore considered out of the scope of the proposed rule. Some of the out-of-scope comments were related to a wide range of aspects of the Hospital Readmissions Reduction Program and its readmissions measures. For example, there were recommendations for statutory changes to the program payment structure and previously finalized program definitions, changes to the program goals, and the frequency of assessing and reporting performance on measures. Notably, there were many public comments on risk adjustment for sociodemographic status (SDS) at the patient-level and hospital-level. While we appreciate the commenters' feedback, we consider these topics to be

out of scope of the proposed rule. Therefore, we are not addressing most of them in this final rule. However, we are addressing topic of the risk-adjustment for SDS in this final rule because of the volume of public comments and the importance of this topic for outcome measures in payment programs. We are also addressing the impact of declining admissions on the Hospital Readmissions Reduction Program.

All other out-of-scope topics will be taken into consideration when developing policies and program requirements for future years.

Comment: Several commenters suggested that all readmissions measures in the Hospital Readmissions Reduction Program should be risk-adjusted to reflect the hospital's inpatient population and account for sociodemographic factors, including income, education level, and poverty rate. The commenters suggested that, without an SDS adjustment, large hospitals, major teaching hospitals, and hospitals with a higher DSH proportion (indicating higher levels of care for more vulnerable patients) are more likely to be penalized for community factors outside of a hospital's control (for example, availability of primary care, physical therapy, rehabilitative services, and family support).

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures. To date, we have found that hospitals that care for large proportions of patients of low sociodemographic status are capable of performing well on our measures (we refer readers to the 2014 Chartbook, pages 48–57, 70–73, and 78, at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*).

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: A number of commenters recommended that CMS examine the effect of declining hospital admissions on readmission penalties, and consider whether future revisions to the readmission measure formulas are needed.

Response: We thank the commenters for their recommendation. We note that the basic readmissions formulas for the Hospital Readmissions Reduction Program are specified in the statute. We will continue to monitor admissions rates and the effects of changes in admission rates on measures performance in our quality reporting and incentive programs.

4. Refinement of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization Measure Cohort for the FY 2017 Payment Determination and Subsequent Years

a. Background

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24490 through 24492), for the FY 2017 payment determination and subsequent years, we proposed a refinement of the currently NQF-endorsed CMS Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) (hereafter referred to as the CMS 30-Day Pneumonia Readmission Measure (NQF #0506)), which would have expanded the measure cohort. For the purposes of describing the refinement of this measure, we noted that ''cohort'' is defined as the hospitalizations, or ''index admissions,'' that are included in the measure. This cohort is the set of hospitalizations that meet all of the inclusion and exclusion criteria, and we proposed an expansion to this set of hospitalizations. The previously adopted CMS 30-Day Pneumonia Readmission Measure (NQF #0506) included hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia. For measure cohort details of the prior version of the measure, we refer readers to the measure methodology report and measure risk adjustment statistical model on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

The proposed measure refinement would have expanded the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. We suggested that including such patients would better represent the complete population of a hospital's patients who are receiving clinical management and treatment for pneumonia, and ensure the measure includes more complete and comparable populations across hospitals. In addition, use of comparable populations would reduce measurement bias resulting from different coding practices seen across hospitals. We stated our belief that measure results derived from refinement of the measure cohort in the manner we proposed would improve the measure's assessment of avoidable readmissions and more accurately reflect quality and outcome for pneumonia patients. The determination to refine the measure cohort was based on our evaluation of both the frequency and variation in utilization of these diagnosis codes, and as such coding practices have been described in recently published studies. The rationale for expanding the measure cohort for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) was further described in section VIII.A.6.b. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24564 through 24566) under our discussion of proposed refinements for the Hospital IQR Program.

b. Overview of the Measure Cohort Change

The proposed measure refinement would have expanded the cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who

also have a secondary diagnosis of pneumonia that is coded as present on admission. The data sources, exclusion criteria, and assessment of the outcome of readmission remained unchanged.

The proposed refinement of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) with this expanded measure cohort was reviewed by the Measure Applications Partnership (MAP), which conditionally supported use of the measure update for the Hospital Readmissions Reduction Program pending NQF review of the measure update and appropriate consideration under the NQF SDS pilot, if required, as detailed in its Pre-Rulemaking 2015 MAP Recommendations Report available at: *https://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

We note that during the MAP Hospital Workgroup and MAP Coordinating Committee in-person meetings, some members discussed the benefit of a phased approach that would first allow for public reporting of the refined measure before implementing it in a pay-for-performance program in order to allow providers to gain experience with the measure refinement, while other members expressed concern that this would delay implementation of an improved measure and also cause alignment issues and potential confusion among providers. The MAP supported the use of the measure refinement without stipulating prior public reporting as a condition of support. However, we acknowledge the importance of this consideration and took it into account when determining to propose implementation of the measure refinement in the Hospital Readmissions Reduction Program beginning with the FY 2017 payment determination.

We considered other options in proposing when to implement the refinement of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) in the Hospital Readmissions Reduction Program, including the option to implement the measure refinement beginning with the FY 2018 payment determination. Delaying implementation of the measure refinement until FY 2018 would allow hospitals to gain more experience with the impact of the measure refinement on their measure results and excess readmissions ratios. However, it also would mean delaying use of an improved measure that we believe would better represent the complete population of a hospital's pneumonia patients and better reflect comparable pneumonia patients across hospitals. Delaying implementation of the measure refinement for the Hospital Readmissions Reduction Program could also potentially increase confusion among hospitals as well as raise alignment issues with other CMS hospital inpatient quality reporting and payment programs that use the same measure.

After considering these options, we proposed to begin with the FY 2017 payment determination to implement the refinement of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) in the Hospital Readmissions Reduction Program. We believed that after weighing the considerations, the proposed measure refinement should be incorporated into the Hospital Readmissions Reduction Program as soon as statutorily and operationally feasible, primarily because improving the measure in the manner we proposed would greatly improve the measure's assessment of quality and outcome for pneumonia patients and, therefore, its implementation should not be unnecessarily delayed.

c. Risk Adjustment

The risk adjustment and statistical modeling approach as well as the measure calculation for the proposed measure remained unchanged from the previously adopted measure. However, we did confirm the use of current risk-adjustment variables in the expanded measure cohort by confirming their association with the outcome. We also examined additional risk variables leading to the addition of a few additional risk variables in the measure.

d. Calculating the Excess Readmissions Ratio

The proposed refinement of the measure cohort for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) would have used the same methodology and statistical modeling approach as the previously adopted in the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the Hospital Readmissions Reduction Program, as well as the other Hospital Readmissions Reduction Program measures. We published a detailed description of how the readmission measures estimate the excess readmissions ratios in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380 through 53381).

We noted that the set of hospitals for which this refined measure would be calculated for the Hospital Readmissions Reduction Program would differ from those used in calculations for the Hospital IQR Program. The Hospital Readmissions Reduction Program includes only subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act (and, if not waived from participating, those hospitals paid under section 1814(b)(3) of the Act), while the Hospital IQR Program calculations include non-IPPS hospitals, such as CAHs, cancer hospitals, and hospitals located in the Territories of the United States. However, we believed that adoption of the refinement to the measure cohort for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) would be appropriate for both programs.

In summary, we proposed a refinement of the NQF-endorsed CMS 30-Day Pneumonia Readmission Measure (NQF #0506), which would expand the measure cohort, in the Hospital Readmissions Reduction Program for the FY 2017 payment determination and subsequent years.

We invited public comment on this proposal.

Comment: Many commenters supported CMS' proposed refinement of the NQF-endorsed CMS 30-Day Pneumonia Readmission Measure (NQF #0506), stating that the revised cohort would more completely cover the inpatient hospital patient population.

Response: We appreciate the commenters' support.

Comment: Many commenters expressed concern that patients with acute respiratory failure present higher acuity than average community acquired pneumonia patients, as they often arrive at the hospital intubated or in immediate need of ventilator support and frequently have pre-existing lung disease and pathology, severe influenza, or viral pneumonia. Several commenters also stated that the proposed inclusion of patients with respiratory failure may result in the double counting of cases in two different readmission measures (pneumonia and chronic obstructive pulmonary disease (COPD)), as both the proposed revised pneumonia measure and the COPD measure could include the same cases when respiratory failure is the primary diagnosis and COPD and pneumonia are listed as the secondary diagnoses. One commenter was particularly concerned about the inclusion of sepsis patients with other infectious diseases in addition to pneumonia, severe illness consistent with severe sepsis, or prolonged intubation.

Response: We thank the commenters for their recommendations, and appreciate their concerns regarding the extent of the cohort expansion particularly with regard to inclusion of patients with a primary diagnosis of respiratory failure and severe sepsis.

Upon further evaluation and analysis of the impact of the proposed measure, and in response to the public comments, we are finalizing a modified version of the expanded pneumonia cohort from what we had specified in the proposed rule. The modified version includes patients with a principal discharge diagnosis of pneumonia or aspiration pneumonia, and patients with a principal discharge diagnosis of sepsis with a secondary diagnosis of pneumonia coded as present on admission. However, we are not including patients with a principal discharge diagnosis of respiratory failure or patients with a principal discharge diagnosis of sepsis if they are coded as having severe sepsis as we had previously proposed.

As we stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24490 through 24492), the purpose of expanding the cohort of the current pneumonia readmission measure is to include a broader spectrum of pneumonia patients and respond to changes in coding practices that were potentially biasing estimates of the performance of hospitals. Additional analyses were conducted after the proposed rule was published as part of the measure reevaluation and re-specification process. These analyses revealed challenges to the risk adjustment methodology with respect to patients with severe sepsis and respiratory failure, and revealed that the proposed cohort expansion would exacerbate the bias in the existing measure that it was intended to mitigate. Specifically, hospital coding frequency was found to be even more strongly, and inversely, associated with performance. Therefore, we modified the refined cohorts to address this bias.

The decision to finalize the modified version is also consistent with clinical practice, as these sickest patients often receive care in an intensive care unit and other specialized interventions (such as ventilator support) that is clinically distinct from the care provided to patients with less severe forms of pneumonia. The modified version has also been determined to be statistically robust, such that risk-standardization accounted for case-mix differences across hospitals, without being confounded by hospital coding patterns. These changes also are consistent with public comments received in response to the FY 2016 IPPS/LTCH PPS proposed rule. For details on the rationale for the cohort expansion, the analyses supporting the re-specified cohort we are finalizing instead of the specifications previously proposed, and the full specification and results of the measure as adopted in this final rule, we refer readers to the measure methodology report for the finalized measure in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

This additional analysis indicates that the modified version of the expansion of the cohort we are finalizing responds to potential bias in the current measure, and that risk adjustment is adequate. We believe this revised cohort expansion produces a measure that does not favor or disadvantage hospitals on the basis of their coding practices. We also believe the revised cohort we are adopting still effectively broadens the cohort of patients included in the measure to be more clinically comprehensive (bringing in sepsis and aspiration pneumonia patients) in relation to what we previously proposed. Finally, we believe that we also are being responsive to commenters' concerns by not including those patients that are most severely ill on arrival (those with severe sepsis and respiratory failure, as included in the previously proposed version), because these patients' increased risk is challenging to appropriately account for across hospitals.

We note that because patients with a principal discharge diagnosis of respiratory failure are no longer included in the modified version of the cohort, there is no opportunity for readmissions to be counted in both the pneumonia and COPD readmission measures.

Comment: A number of commenters argued that patients with a diagnosis of sepsis and secondary diagnosis of pneumonia have a higher predicted mortality and readmission risk, and often have multiple comorbidity conditions, which are prone to exacerbation during the index admission. One commenter argued the inclusion of sepsis in the pneumonia readmission measures creates the possibility of duplicate penalties. Another commenter argued that additional conditions needed to be added to the risk adjustment for sepsis patients. Another commenter was particularly concerned about the inclusion of sepsis patients with severe sepsis.

Response: We thank the commenters for their comments. As we discussed, we have conducted additional analysis regarding the impact of the modified cohort, and in response to public comments and the results of this analysis, we are finalizing the modified version of the expanded pneumonia cohort from what we had specified in the proposed rule. The modified version of the expanded pneumonia cohort includes patients with a principal discharge diagnosis of pneumonia or aspiration pneumonia, and patients with a principal discharge diagnosis of sepsis with a secondary diagnosis of pneumonia coded as present on admission, but does not include patients with a principal discharge diagnosis of respiratory failure or patients coded as having severe sepsis. Based on the testing and analysis we conducted, we believe that the risk adjustment we are finalizing adequately accounts for the varying severity and comorbidities of patients across the finalized cohort, and that hospitals will not be unfairly penalized for treating sicker patients. Based on our additional evaluation, we confirmed that the approach to risk-adjustment for the modified measure was effective, as hospital coding frequency was not associated with performance on the readmission measure.

We had previously proposed including the presence of sepsis or respiratory failure in the index admission as covariates, or risk-adjusters, in the model. However, analyses conducted subsequent to publication of the FY 2016 IPPS/LTCH PPS proposed rule revealed that this approach would exacerbate the bias in the existing measure that it was intended to mitigate as such patients' increased risk was challenging to appropriately account for across hospitals. Therefore, in the modified measure, the risk adjustment factors used in the publicly reported version of the readmission measure were retained and one new risk-adjustment variable (respiratory dependence/tracheostomy (CC77)) was added. No additional risk adjustment variables were added for the patients included in the expanded cohort (that is, aspiration pneumonia and sepsis patients).

We conducted additional analyses and found that limiting the measure expansion to aspiration pneumonia patients and sepsis patients without including risk adjustment for these alternate principal diagnoses of respiratory failure and severe sepsis was the most feasible approach that brought in a large portion of patients currently excluded from the measure but mitigated the biases introduced by hospital coding patterns. Specifically, our analysis indicated that under the revisions we are adopting, hospital performance among hospitals with higher rates of patients with sepsis or

aspiration pneumonia is similar to those with fewer such patients, suggesting that the finalized risk adjustment methodology adequately accounts for the differences in risk among the subgroups of patients. For details on the finalized risk adjustment model, we refer readers to the measure methodology report for the finalized measure in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

Comment: Several commenters objected to the addition of aspiration pneumonia to the revised cohort. A number of commenters suggested that adding aspiration pneumonia to the current measure denominator would result in a 26.4 percent increase in the patient cohort for major teaching hospitals, compared to a 20.6 percent increase for nonteaching hospitals, raising concerns that the modification would adversely affect teaching hospital measure performance.

Response: We appreciate the commenters' concerns regarding the inclusion of aspiration pneumonia in the finalized cohort. We believe that inclusion of aspiration pneumonia patients in the expanded cohort we are adopting in this final rule is appropriate to broaden the portion of patients otherwise excluded from the measure. While the pathological causes of aspiration pneumonia are slightly different from the causes of community acquired pneumonia, in routine clinical practice it can be very challenging for physicians to differentiate aspiration syndromes, including pneumonitis and pneumonia, from other types of pneumonia included in the measure. This is reflected in tremendous variation across hospitals in the use of aspiration pneumonia diagnosis codes. This variation suggests that hospitals are not consistently distinguishing between these conditions as distinct subtypes. Moreover, the treatment of patients hospitalized for pneumonia or aspiration pneumonia or sepsis due to pneumonia is very similar and involves antibiotics, IV fluids, and symptom management. In addition, although some patients with aspiration pneumonia have a higher predicted mortality or readmission risk, many of the associated comorbidities are captured in the finalized measure's risk adjustment methodology, including clinical history of stroke, neuromuscular disease, and dementia.

We find that hospital performance among hospitals with higher rates of patients with aspiration pneumonia is similar to those with fewer such patients, suggesting that the finalized risk adjustment methodology adequately accounts for the differences in risk among the subgroups of patients. Although major teaching hospitals may have larger increases in the size of their cohorts due to this modification, that should not impose additional burden on these hospitals (as this is a claims-based measure and does not require data collection), nor should it lead to worse performance on the measure by major teaching hospitals due to adequate risk-adjustment for the aspiration pneumonia patients.

The analyses of this measure indicated that an approximately equal numbers of hospitals, and, specifically, equal numbers of teaching hospitals, improved or worsened their categorical performance under the modified version of the measure we are adopting in this final rule. We did not see evidence that teaching hospitals will be differentially burdened or adversely affected on the basis of this modification to the measure. We believe that while some variation in case-mix is to be expected, the risk adjustment methodology we have adopted takes into account many of the risk factors for aspiration pneumonia (including age, neurologic disease, and dementia), and adequately controls for these differences. We found minimal association between aspiration coding patterns and risk-standardized readmission rates. For details on the measure as finalized, we refer readers to the measure methodology report for the finalized measure in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

Comment: A number of commenters expressed concern that the revised measure only received conditional support from the MAP for use in the Hospital Readmissions Reduction Program pending NQF review of the measure update and appropriate consideration under the NQF sociodemographic status pilot. The commenters noted that NQF review and consideration of the measure under the sociodemographic status pilot have not yet occurred, and recommended postponing implementation of the measure refinement until these conditions have been met. Several commenters also suggested that the revisions to the measure cohort were significant enough that the revised measure was in many respects a new, rather than a revised, measure. Some commenters expressed concern that consumers may be confused or unaware of the differences between the revised measure we are adopting in this final rule and the previously adopted version of the measure.

Response: We thank the commenters for their thoughts regarding the MAP review and NQF endorsement. We note that NQF endorsement is not a formal requirement for the refinement of Hospital Readmissions Reduction Program measures. We plan to submit the modified version of the measure that we are adopting in this final rule to the NQF for endorsement maintenance as part of the Pulmonary Project when the project has its call for measures later this year. In addition, the modified version of this measure will be included in the NQF SDS pilot as part of the endorsement maintenance process. While we believe both of these processes will provide valuable input on this measure, one of the most important goals of the Hospital Readmissions Reduction Program is to more completely cover the inpatient hospital patient population, and we have performed extensive additional analyses to evaluate the impact of the revised measure. We did not want to delay the implementation of this important revision until after the completion of the NQF endorsement process, as we believe that improving the measure in the form we are finalizing will greatly improve the measure's assessment of quality and outcome for pneumonia patients, and further the goals of the Hospital Readmissions Reduction Program. Therefore, we believe that it is appropriate to implement the measure in the finalized timeframe.

Although the modified version of the cohort expansion for this measure that we are finalizing will increase the number of patients included in the measure and change the national readmission rate, we do not believe this constitutes a new measure. The intent of the measure has not changed since initial development and NQF endorsement. The finalized readmission measure cohort will be approximately 15 percent smaller than originally proposed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24491). In addition, section 1886(q)(5)(B) of the Act allows the use of a feasible and practical measure that has not been NQF-endorsed as long as due consideration has been given to the measure. After extensive consideration, we believe adoption of the modified version of this measure beginning with the FY 2017 payment determination is feasible, practical, and important for

improving the assessment of quality and outcome for pneumonia patients such that implementation should not be unnecessarily delayed. For details of the finalized measure that we are adopting in this final rule, we refer readers to the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We will note which version of the measure is displayed on *Hospital Compare* to minimize any potential confusion for consumers.

Comment: Several commenters objected to studies CMS cited in the proposed rule regarding the impact of coding differences across hospitals on the 30-Day Pneumonia Readmission Measure (NQF#0506), arguing that these studies examine in-hospital mortality rates, but not 30-day readmission rates. The commenters further argued that these studies do not examine the cause of the coding differences, and that additional study on the effect of the revised measure is needed prior to implementation in the Hospital Readmissions Reduction Program.

Response: We thank the commenters for their responses. We note that, although the original medical research prompting the expansion of the measure cohort used only inpatient mortality as the outcome, we evaluated the concerns about potential bias due to differences in coding practice among hospitals using the 30-day readmission and mortality measures and found patterns as described in the literature. This subsequent evaluation lead us to undergo the measure reevaluation work that resulted in the proposed change to the cohort as described in the FY 2016 IPPS/LTCH PPS proposed rule and the modified version that we are adopting in this final rule. Furthermore, a more recent publication has confirmed similar risks using 30-day readmission and mortality rates in Medicare beneficiaries. For details of this publication and the modified version of the expanded measure cohort that we are adopting in this final rule, we refer readers to the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: A number of commenters requested that CMS postpone implementation of the revised measure in order to allow hospitals more time to prepare for the impact of any changes to their rates and to develop or evaluate interventions for the expanded cohort. Many commenters also asked CMS to provide dry run data on *Hospital Compare* for hospitals to review prior to implementation, with some requesting a year of public reporting prior to implementation. Other commenters noted that the performance period for the FY 2017 payment year will have ended by the time this final rule is published, which will limit the ability of hospitals to improve performance prior to payment impact.

Several commenters also requested delayed implementation of the revised measure in order to provide time to assess the impact of the upcoming transition to ICD–10 on the revised pneumonia readmission measure, and suggested that CMS not make any changes to the current pneumonia measure until any impact can be evaluated. The commenters asked that CMS provide data on the revised measure, including ICD–9 and ICD–10 detailed codes, to allow hospitals to assess impact prior to implementation.

Response: We thank the commenters for their comments and acknowledge their concerns urging delayed implementation of the measure. However, we believe that it is important to expand the portion of the hospital inpatient population covered by the Hospital Readmissions Reduction Program at this time. Most hospitals have been working on addressing the key topics associated with readmissions, including coordination of care and care transitions, for some time, and we do not believe delayed implementation will be of benefit to patients.

With respect to the upcoming ICD–10 transition, we are aware of stakeholder concerns about the potential impacts to hospital performance on quality measures when ICD–10 is implemented on October 1, 2015, as well as their calls for more extensive testing to understand the impacts before any payments or penalties are implicated. As part of ICD–10 transition planning that has taken place over the past several years, we have performed testing and analyses across the agency with respect to system readiness and claims reimbursement, and we have provided extensive education and outreach to providers, vendors, and other payers. Our systems for quality programs have been tested and will continue to be tested as ICD–10 data are submitted in order to ensure the accuracy of measure calculations and to monitor and assess the translation of measure specifications to ICD–10, potential coding variation, and impacts on measure performance and payment incentive programs. We will continue to work with stakeholders during the ICD–10 transition to monitor and assess impacts and to address any potential issues that may occur.

With respect to the modified version of the expanded measure cohort that we are adopting in this final rule, we refer commenters to the measure methodology report for the details of the measure in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Based on further analyses and testing of this measure and after consideration of the public comments we received, we are finalizing a modified version of the expanded pneumonia cohort from the version we specified in the FY 2016 IPPS/LTCH PPS proposed rule. The modified version of the expanded pneumonia cohort includes patients with a principal discharge diagnosis of pneumonia or aspiration pneumonia, and patients with a principal discharge diagnosis of sepsis with a secondary diagnosis of pneumonia coded as POA, but does not include patients with a principal discharge diagnosis of respiratory failure or patients with a principal discharge diagnosis of sepsis if they are coded as having severe sepsis.

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 Web site 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 Web site on the Resources page at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995*.

6. Floor Adjustment Factor for FY 2016 (§ 412.154(c)(2))

Section 1886(q)(3)(A) of the Act defines the ''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. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor, which is set at 0.97 for FY 2015 and subsequent fiscal years. We codified the floor adjustment factor at § 412.154(c)(2) of the regulations (77 FR 53386).

Consistent with section 1886(q)(3) of the Act, codified at § 412.154(c)(2), the adjustment factor is either the greater of the ratio or, for FY 2015 and subsequent fiscal years, a floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2015 and subsequent fiscal years, a hospital subject to the Hospital Readmissions Reduction Program will have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

7. Applicable Period for FY 2016

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 adjustments 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.

Consistent with the definition specified at § 412.152, we established that the applicable period for FY 2014 under the Hospital Readmissions Reduction Program is the 3-year period from July 1, 2009, to June 30, 2012. That is, we determined the excess readmissions ratios and calculate the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2014 using data from the 3-year time period of July 1, 2009 through June 30, 2012, as this was the most recent available 3-year period of data upon which to base these calculations (78 FR 50669).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 40 through 50041), for FY 2015, consistent with the definition specified at § 412.152, we finalized an ''applicable period'' for the Hospital Readmissions Reduction Program to be the 3-year period from July 1, 2010 through June 30, 2013. That is, we determined the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2015 using data from the 3-year time period of July 1, 2010 through June 30, 2013.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24492), for FY 2016, consistent with the definition specified at § 412.152, we proposed an ''applicable period'' for the Hospital Readmissions Reduction Program to be the 3-year period from July 1, 2011 through June 30, 2014. In other words, we proposed that the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2016 using data from the 3-year time period of July 1, 2011 through June 30, 2014.

Comment: Some commenters requested that CMS revise the applicable time period to only include a shorter time period such as the most recent year.

Response: We note that we addressed this concern in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380), and that we use a 3-year period of index admissions to increase the number of cases per hospital used for measure calculation, which improves the precision of each hospital's readmission estimate. Although this approach utilizes older data, it also identifies more variation in hospital performance and still allows for improvement from one year of reporting to the next.

After consideration of the public comments we received, we are finalizing as proposed the applicable period of the 3-year time period of July 1, 2011 to June 30, 2014 to calculate the excess readmission ratios and the readmission payment adjustment factors for FY 2016.

8. Calculation of Aggregate Payments for Excess Readmissions for FY 2016

a. Background

Section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. 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. The definition of ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges,'' as well as a methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges) are codified at § 412.154(c)(2) of the regulations (77 FR 53387).

Section 1886(q)(4) of the Act sets forth the definitions of ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' for an applicable hospital for the applicable period. The term ''aggregate payments for excess readmissions'' is defined in section 1886(q)(4)(A) of the Act as for a hospital for an applicable period, the sum, for applicable conditions of the product, for each applicable condition, of (i) The base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1. We codified this definition of ''aggregate payments for excess readmissions'' under the regulations at § 412.152 as the product, for each applicable condition, of: (1) The base operating DRG payment amount for the hospital for the applicable period for such condition; (2) the number of admissions for such condition for the hospital for the applicable period; and (3) the excess readmissions ratio for the hospital for the applicable period minus 1 (77 FR 53675).

The excess readmissions ratio is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmissions ratio as the ratio of ''risk-adjusted readmissions based on actual readmissions'' for an applicable hospital for each applicable condition, to the ''risk-adjusted expected readmissions'' for the applicable hospital for the applicable condition. The methodology for the calculation of the excess readmissions ratio was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673).

''Aggregate payments for excess readmissions'' is the numerator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program (as described in further detail later in this section).

The term ''aggregate payments for all discharges'' is defined at section 1886(q)(4)(B) of the Act as for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period. ''Aggregate payments for all discharges'' is the denominator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. We codified this definition of ''aggregate payments for all discharges'' under the regulations at § 412.152 (77 FR 53387).

We finalized the inclusion of one additional applicable condition, Patients Readmitted Following Coronary Artery Bypass Graft (CABG) Surgery, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50033 through 50039) effective for FY 2017. We will address the inclusion of this additional measure in the calculation of the readmissions payment adjustment for FY 2017 in the FY 2017 rulemaking.

b. Calculation of Aggregate Payments

As discussed above, when calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payments for the applicable period. ''Aggregate payments for excess readmissions'' (the numerator) is defined as the sum, for applicable conditions of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1.

When determining the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period to calculate the excess readmissions ratio. We use MedPAR claims data as our data source for determining aggregate payments for excess readmissions and aggregate payments for all discharges, as this data source is consistent with the claims data source used in IPPS rulemaking to determine IPPS rates.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24493 through 24496), for FY 2016, we proposed to use MedPAR claims with discharge dates that are on or after July 1, 2011, and no later than June 30, 2014. 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 (that is, the March updates of the respective Federal fiscal year MedPAR files) for the final rules.

The FY 2011 through FY 2014 MedPAR data files can be purchased from CMS. Use of these files allows the public to verify the readmissions adjustment factors. Interested individuals may order these files through the CMS Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and detailed instructions for how to order the data sets. Persons placing an order must send the following: A Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check for $3,655 to:

- If using the U.S. Postal Service: Centers for Medicare and Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520.
- If using express mail: Centers for Medicare and Medicaid Services, OFM/Division of Accounting—RDDC, Mailstop C#-07-11, 7500 Security Boulevard, Baltimore, MD 21244–1850.

In the FY 2016 IPPS/LTCH PPS proposed rule, we proposed to determine aggregate payments for excess readmissions and aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2011, and no later than June 30, 2014. However, we noted that, for the purpose of modeling the proposed FY 2016 readmissions payment adjustment factors for the FY 2016 IPPS/LTCH PPS proposed rule, we used excess readmissions ratios for applicable hospitals from the FY 2015 Hospital Readmissions Reduction Program applicable period. For this FY 2016 IPPS/LTCH PPS final rule, applicable hospitals will have had the opportunity to review and correct data from the proposed FY 2016 applicable period of July 1, 2011 to June 30, 2014, before they are made public under our policy regarding the reporting of hospital-specific information, which we discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).

In the FY 2016 IPPS/LTCH PPS proposed rule, for FY 2016, we proposed to use MedPAR data from July 1, 2011 through June 30, 2014. Specifically, in the FY 2016 IPPS/LTCH PPS proposed rule, we used the March 2012 update of the FY 2011 MedPAR file to identify claims within FY 2011 with discharges dates that are on or after July 1, 2011, the March 2013 update of the FY 2012 MedPAR file to identify claims within FY 2012, the March 2014 update of the FY 2013 MedPAR file to identify claims within FY 2013, and the December 2014 update of the FY 2014 MedPAR file to identify claims within FY 2014 with discharge dates no later than June 30, 2014. For this final rule, we proposed to use the same MedPAR files as listed above for claims within FY 2011, FY 2012 and FY 2013. For claims within FY 2014, we proposed to use in the final rule the March 2015 update of the FY 2014 MedPAR file.

In order to identify the admissions for each condition, to calculate the aggregate payments for excess readmissions for an individual hospital, for FY 2016, we proposed to identify each applicable condition using the ICD–9–CM codes used to identify applicable conditions to calculate the excess readmissions ratios. (Although the compliance date for the ICD–10–CM and ICD10–PCS code sets is October 1, 2015 (79 FR 45128 through 45134), these proposed policies apply to data periods prior to this compliance date.) Under our existing policy, we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period (76 FR 51669). The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. These codes are posted on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50041 through 50048) for a discussion of how we identify the applicable conditions to calculate the aggregate payments for excess readmissions for FY 2015. For FY 2016, we proposed to follow this same approach.

In the FY 2016 IPPS/LTCH PPS proposed rule, for FY 2016, we proposed to continue to apply the same exclusions to the claims in the MedPAR file as we applied for FY 2015 for the current applicable conditions. For FY 2016, in order to have the same types of admissions to calculate aggregate payments for excess readmissions as is used to calculate the excess

readmissions ratio, we proposed to identify admissions for the AMI, HF, PN, THA/TKA, COPD applicable conditions, for the purposes of calculating aggregate payments for excess readmissions as follows:

- We would exclude admissions that are identified as an applicable condition if the patient died in the hospital, as identified by the discharge status code on the MedPAR claim.
- We would exclude admissions identified as an applicable condition for which the patient was transferred to another provider that provides acute care hospital services (that is, a CAH or an IPPS hospital), as identified through examination of contiguous stays in MedPAR at other hospitals.
- We would exclude admissions identified as an applicable condition for patients who are under the age of 65, as identified by linking the claim information to the information provided in the Medicare Enrollment Database.
- For conditions identified as AMI, we would exclude claims that are same day discharges, as identified by the admission date and discharge date on the MedPAR claim.
- We would exclude admissions for patients who did not have Medicare Parts A and B FFS enrollment in the 12 months prior to the index admission, based on the information provided in the Medicare Enrollment Database.
- We would exclude admissions for patients without at least 30 days post-discharge enrollment in Medicare Parts A and B FFS, based on the information provided in the Medicare Enrollment Database.
- We would exclude all multiple admissions within 30 days of a prior index admission's discharge date, as identified in the MedPAR file, consistent with how multiple admissions within 30 days of an index admission are excluded from the calculation of the excess readmissions ratio.

These exclusions are consistent with our current methodology, which was established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048).

Furthermore, we would only identify Medicare FFS claims that meet the criteria (that is, claims paid for under Medicare Part C (Medicare Advantage) would not be included in this calculation), 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 2016, we would exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database. This policy is consistent with how admissions for Medicare Advantage patients are identified in the calculation of the excess readmissions ratios under our established methodology. The tables below list the ICD–9–CM codes we proposed to use to identify each applicable condition to calculate the aggregate payments for the excess readmissions proposal for FY 2016. These ICD–9–CM codes also would be used to identify the applicable conditions to calculate the excess readmissions ratios, consistent with our established policy (76 FR 51673 through 51676).

ICD–9–CM CODES TO IDENTIFY PNEUMONIA (PN) CASES

ICD–9–CM code	Description of code
480.0	Pneumonia due to adenovirus.
480.1	Pneumonia due to respiratory syncytial virus.
480.2	Pneumonia due to parainfluenza virus.
480.3	Pneumonia due to SARS-associated coronavirus.
480.8	Viral pneumonia: pneumonia due to other virus not elsewhere classified.
480.9	Viral pneumonia unspecified.
481	Pneumococcal pneumonia [streptococcus pneumoniae pneumonia].
482.0	Pneumonia due to klebsiella pneumoniae.
482.1	Pneumonia due to pseudomonas.
482.2	Pneumonia due to hemophilus influenzae [h. influenzae].
482.30	Pneumonia due to streptococcus unspecified.
482.31	Pneumonia due to streptococcus group a.
482.32	Pneumonia due to streptococcus group b.
482.39	Pneumonia due to other streptococcus.
482.40	Pneumonia due to staphylococcus unspecified.
482.41	Pneumonia due to staphylococcus aureus.
482.42	Methicillin Resistant Pneumonia due to Staphylococcus Aureus.
482.49	Other staphylococcus pneumonia.
482.81	Pneumonia due to anaerobes.
482.82	Pneumonia due to escherichia coli [e.coli].
482.83	Pneumonia due to other gram-negative bacteria.
482.84	Pneumonia due to legionnaires' disease.
482.89	Pneumonia due to other specified bacteria.
482.9	Bacterial pneumonia unspecified.
483.0	Pneumonia due to mycoplasma pneumoniae.
483.1	Pneumonia due to chlamydia.
483.8	Pneumonia due to other specified organism.
485	Bronchopneumonia organism unspecified.
486	Pneumonia organism unspecified.
487.0	Influenza with pneumonia.
488.11	Influenza due to identified novel H1N1 influenza virus with pneumonia.

ICD–9–CM CODES TO IDENTIFY HEART FAILURE (HF) CASES

ICD–9–CM code	Code description
402.01	Hypertensive heart disease, malignant, with heart failure.
402.11	Hypertensive heart disease, benign, with heart failure.

ICD–9–CM CODES TO IDENTIFY HEART FAILURE (HF) CASES—Continued

ICD–9–CM code	Code description
402.91	Hypertensive heart disease, unspecified, with heart failure.
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease.
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified failure and chronic kidney disease stage V or end stage renal disease.
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease.
428.xx	Heart Failure.

ICD–9–CM CODES TO IDENTIFY ACUTE MYOCARDIAL INFARCTION (AMI) CASES

ICD–9–CM code	Description of code
410.00	AMI (anterolateral wall)—episode of care unspecified.
410.01	AMI (anterolateral wall)—initial episode of care.
410.10	AMI (other anterior wall)—episode of care unspecified.
410.11	AMI (other anterior wall)—initial episode of care.
410.20	AMI (inferolateral wall)—episode of care unspecified.
410.21	AMI (inferolateral wall)—initial episode of care.
410.30	AMI (inferoposterior wall)—episode of care unspecified.
410.31	AMI (inferoposterior wall)—initial episode of care.
410.40	AMI (other inferior wall)—episode of care unspecified.
410.41	AMI (other inferior wall)—initial episode of care.
410.50	AMI (other lateral wall)—episode of care unspecified.
410.51	AMI (other lateral wall)—initial episode of care.
410.60	AMI (true posterior wall)—episode of care unspecified.
410.61	AMI (true posterior wall)—initial episode of care.
410.70	AMI (subendocardial)—episode of care unspecified.
410.71	AMI (subendocardial)—initial episode of care.
410.80	AMI (other specified site)—episode of care unspecified.
410.81	AMI (other specified site)—initial episode of care.
410.90	AMI (unspecified site)—episode of care unspecified.
410.91	AMI (unspecified site)—initial episode of care.

ICD–9–CM CODES TO IDENTIFY CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) CASES

ICD–9–CM code	Description of code
491.21	Obstructive chronic bronchitis; With (acute) exacerbation; acute exacerbation of COPD, decompensated COPD, decompensated COPD with exacerbation.
491.22	Obstructive chronic bronchitis; with acute bronchitis.
491.8	Other chronic bronchitis. Chronic: Tracheitis, tracheobronchitis.
491.9	Unspecified chronic bronchitis.
492.8	Other emphysema; emphysema (lung or pulmonary): NOS, centriacinar, centrilobular, obstructive, panacinar, panlobular, unilateral, vesicular. MacLeod's syndrome; Swyer-James syndrome; unilateral hyperlucent lung.
493.20	Chronic obstructive asthma; asthma with COPD, chronic asthmatic bronchitis, unspecified.
493.21	Chronic obstructive asthma; asthma with COPD, chronic asthmatic bronchitis, with status asthmaticus.
493.22	Chronic obstructive asthma; asthma with COPD, chronic asthmatic bronchitis, with (acute) exacerbation.
496	Chronic: nonspecific lung disease, obstructive lung disease, obstructive pulmonary disease (COPD) NOS. NOTE: This code is not to be used with any code from categories 491–493.
518.81*	Other diseases of lung; acute respiratory failure; respiratory failure NOS.
518.82*	Other diseases of lung; acute respiratory failure; other pulmonary insufficiency, acute respiratory distress.
518.84*	Other diseases of lung; acute respiratory failure; acute and chronic respiratory failure.
799.1*	Other ill-defined and unknown causes of morbidity and mortality; respiratory arrest, cardiorespiratory failure.

* Principal diagnosis when combined with a secondary diagnosis of AECOPD (491.21, 491.22, 493.21, or 493.22).

ICD–9–CM CODES TO IDENTIFY TOTAL HIP ARTHROPLASTY/TOTAL KNEE ARTHROPLATY (THA/TKA) CASES

ICD–9–CM code	Description of code
81.51	Total hip arthroplasty.
81.54	Total knee arthroplasty.

For FY 2016, we proposed to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2011 to June 30, 2014, to identify applicable conditions based on the same ICD–9–CM codes used to identify the conditions for the readmissions measures, and to apply the proposed exclusions for the types of admissions discussed above. To calculate aggregate payments for excess readmissions, we proposed to calculate the base operating DRG payment amounts for all claims in the 3-year applicable period for each applicable condition (AMI, HF, PN, COPD and THA/TKA) based on the claims we have identified as described above. Once we have calculated the base operating DRG amounts for all the claims for the five applicable conditions, we proposed to sum the base operating DRG payments amounts by each condition, resulting in five summed amounts, one amount for each of the five applicable conditions. We proposed to then multiply the amount for each condition by the respective excess readmissions ratio minus 1 when that excess readmissions ratio is greater than 1, which indicates that a hospital has performed, with respect to readmissions for that applicable condition, worse than the average hospital with similar patients. Each product in this computation represents the payments for excess readmissions for that condition. We proposed to then sum the resulting products which represent a hospital's proposed ''aggregate payments for excess readmissions'' (the numerator of the ratio). Because this calculation is performed separately for each of the five conditions, a hospital's excess readmissions ratio must be less than or equal to 1 on each measure to avoid CMS' determination that there were payments made by CMS for excess readmissions (resulting in a payment reduction under the Hospital Readmissions Reduction Program). In other words, in order to avoid a payment reduction a hospital's excess readmissions ratio must be less than or equal to 1 on each measure. We note that we did not propose any changes to our existing methodology to calculate ''aggregate payments for all discharges'' (the denominator of the ratio).

We proposed the following methodology for FY 2016 as displayed in the chart below.

FORMULAS TO CALCULATE THE READMISSIONS ADJUSTMENT FACTOR FOR FY 2016

AGGREGATE PAYMENTS FOR EXCESS READMISSIONS = [sum of base operating DRG payments for AMI × (Excess Readmissions Ratio for AMI–1)] + [sum of base operating DRG payments for HF × (Excess Readmissions Ratio for HF–1)] + [sum of base operating DRG payments for PN × (Excess Readmissions Ratio for PN–1)] + [sum of base operating DRG payments for COPD) × (Excess Readmissions Ratio for COPD–1)] + [sum of base operating DRG payments for THA/TKA × (Excess Readmissions Ratio for THA/TKA–1)].

* We note that if a hospital's excess readmissions ratio for a condition is less than/equal to 1, there are no aggregate payments for excess readmissions for that condition included in this calculation.

Aggregate payments for all discharges = sum of base operating DRG payments for all discharges.

RATIO = 1 − (Aggregate payments for excess readmissions/Aggregate payments for all discharges).

Proposed Readmissions Adjustment Factor for FY 2016 is the higher of the ratio or 0.9700.

* Based on claims data from July 1, 2011 to June 30, 2014 for FY 2016.

We invited public comment on these proposals.

Comment: Several commenters recommended changes to the methodology to calculate the readmission payment adjustment factors, many of these similar to comments received in prior rulemaking. MedPAC reiterated several comments regarding the Hospital Readmissions Reduction Program related to the calculation of the readmissions payment adjustment factor, including that the readmission penalty formula is flawed because aggregate penalties remain constant even as national readmission rates decline; the condition-specific penalty per excess readmission is higher for conditions with low readmission rates; and the penalty should roughly equal the cost of excess readmissions over a fixed target level of readmissions. Other commenters also echoed MedPAC's point that the calculation of the readmission payment adjustment factor creates excessive payment reductions that exceed the cost to the Medicare program of the readmission. Other perceived flaws noted by commenters included that the payment adjustment factor should be adjusted to account for socioeconomic factors and that the calculation does not recognize improvement by a hospital in reducing readmissions.

While some commenters asserted that CMS has the authority through rulemaking to modify the calculation of the payment adjustment factor to address these issues, other commenters indicated that these revisions would require a change in statute.

Response: We received similar types of comments in previous rulemaking and we continue to believe that the statute is prescriptive with respect to the calculation of aggregate payments for excess readmissions because it specifies that the ''aggregate payments for excess readmissions'' is the sum for each condition of the product of the operating DRG payment amount for such hospital for such applicable period for such condition and the number of admissions for such condition and the excess readmission ratio minus one. We believe that section 1886(q)(4)(A) of the Act requires us to include all admissions for a condition in the calculation of aggregate payments for excess readmissions. Therefore, we agree with the commenters who indicated that the statutory calculation of the penalty creates a result that the commenters believe to be prescriptive. The commenters who believe we have the discretionary authority to implement an alternative penalty calculation to address their issues did not suggest an adequate statutory basis for such an approach. We continue to believe that we are implementing the provision as required by law.

As noted above, ASPE is conducting research on the issue of risk adjustment for sociodemographic status as directed by the IMPACT Act, and expects to issue a report to Congress, including recommendations for improvements to the Hospital Readmissions Reduction Program based on that research.

Comment: Some commenters continue to believe that, by including admissions denied by the CMS RACs, a hospital would be penalized twice for the same admission—once by the RAC denial and a second time by having the

admission included in the readmission payment penalty.

Response: As we have explained in prior rulemaking, given the timing of the RAC audits and the updates of the SAF and MedPAR files used to calculate the readmissions measures and readmissions payment adjustment factors, we are not certain that all denied claims will be reflected in our claims files at the time of our calculations under the Hospital Readmissions Reduction Program. However, we continue to believe that using these updates of the MedPAR and SAF files is consistent with IPPS ratesetting and allows for transparency for the public to obtain this dataset for replication. Furthermore, inpatient stays that are denied payment under Medicare Part A typically remain classified as inpatient stays, and can be billed to Medicare Part B as an Medicare Part B inpatient stay. These inpatient stays that are denied payment under Medicare Part A will typically continue to count as a qualifying inpatient stay for other payment purposes such as qualifying for SNF benefits and Medicare DSH patient days. Therefore, we continue to believe that it is appropriate to include these admissions in the Hospital Readmissions Reduction Program.

We did not receive any public comments generally objecting to the other proposed aspects of the calculation of aggregate payments for excess readmissions for FY 2016, such as the specific ICD–9 codes used in the calculation and the data sources for calculation.

After considering the public comments we received, we are finalizing our proposed calculation of aggregate payments for excess readmissions without modification.

9. Extraordinary Circumstance Exception Policy for the Hospital Readmissions Reduction Program Beginning in FY 2016 and for Subsequent Years

a. Background

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28117), we welcomed public comment on our proposal to adopt an extraordinary circumstance exception policy for the Hospital Readmissions Reduction Program. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048), we indicated that we received many comments in support of CMS establishing a formal extraordinary circumstance exception policy for the Hospital Readmissions Reduction Program. We also previously indicated that any specific proposals related to the implementation of an extraordinary circumstance exception policy would be proposed through rulemaking with an opportunity for public comment. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24497), we agreed with commenters that there may be periods of time during which a hospital is not able to submit all claims (from which readmission measures data are derived) in an accurate or timely fashion due to an extraordinary circumstance beyond its control. Section 1886(q)(5)(D) of the Act permits the Secretary to determine the ''applicable period'' for readmissions data collection, and we believe that the statute allows us to determine that the period not include times when hospitals may encounter extraordinary circumstances.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24497), we proposed adopting an extraordinary circumstance exception policy for the Hospital Readmissions Reduction Program beginning in FY 2016 and for subsequent years. This policy was similar to the extraordinary circumstance exception policy for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended § 412.140(c)(2) to refer to ''extension or exemption'' instead of the former ''extension or waiver''). We also considered how best to align an extraordinary circumstance exception policy for the Hospital Readmissions Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital VBP Program, to the extent feasible.

In the proposed rule (80 FR 24497), we also considered the feasibility and implications of excluding data for certain readmission measures for a limited period of time from the calculations for a hospital's excess readmissions ratios for the applicable performance period. By minimizing the data excluded from the program, this approach would enable affected hospitals to continue to participate in the Hospital Readmissions Reduction Program for a given fiscal year if they otherwise continue to meet applicable measure minimum threshold requirements. We believe that this approach could help alleviate the reporting burden for a hospital that is adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the Hospital Readmissions Reduction Program.

b. Requests for an Extraordinary Circumstance Exception

As we stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24497), based upon our prior experience with the Hospital IQR Program and the Hospital VBP Program, we anticipate the need to provide exceptions to only a small number of hospitals affected by a natural disaster or other extraordinary circumstance. During the review of a hospital's request for an extraordinary circumstance exception, we will maintain the general principle that providing high quality of care and ensuring patient safety is of paramount importance, especially in difficult circumstances. We do not intend to allow a hospital to use this proposed policy and the request process to seek exclusion from the Hospital Readmissions Reduction Program in its entirety for a given fiscal year(s) solely because of experiencing an extraordinary circumstance. Rather, we intend to provide relief for a hospital whose ability to accurately or timely submit all of its claims (from which readmission measures data are derived) has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24497 through 24498) we proposed that the request process for an extraordinary circumstance exception begin with the submission of an extraordinary circumstance exception request form by a hospital within 90 calendar days of the natural disaster or other extraordinary circumstance. We believe that the 90-calendar day timeframe is an appropriate period of time for a hospital to determine whether to submit an extraordinary circumstance exception request. It is also the same length of time as the current time period allowed under the Hospital VBP Program. Under this policy, a hospital will be able to request a Hospital Readmissions Reduction Program extraordinary circumstance exception at the same time it may request similar exceptions under the Hospital IQR Program (§ 412.140(c)(2)), the Hospital VBP Program (78 FR 50704 through 50706), and the HAC Reduction Program (which we are finalizing in section IV.G.8.b. of the preamble to this final rule). The extraordinary circumstance exception

request form will be made available on the QualityNet Web site.

The following minimum set of information will be required to submit the request:

- Hospital CCN;
- Hospital name;
- Hospital Chief Executive Officer (CEO) and any other designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address; a post office box address is not acceptable);
- Hospital's reason for requesting an exception, including:

++ CMS program name (the Hospital Readmissions Reduction Program);

++ The measure(s) and submission quarters affected by the extraordinary circumstance that the hospital is seeking an exception for should be accompanied with the specific reasons why the exception is being sought; and

++ How the extraordinary circumstance negatively impacted performance on the measure(s) for which an exception is being sought;

- Evidence of the impact of the extraordinary circumstances, including but not limited to, photographs, newspaper, and other media articles; and
- The request form must be signed by the hospital's CEO or designated non-CEO contact and submitted to CMS.

The same set of information is currently required under the Hospital IQR Program and the Hospital VBP Program on the request form from a hospital seeking an extraordinary circumstance exception with respect to these programs. The specific list of required information is subject to change from time to time at the discretion of CMS.

Following receipt of the request form, CMS will: (1) Provide a written acknowledgement of receipt of the request using the contact information provided in the request form to the CEO and any additional designated hospital personnel; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision. Under this policy, we will review each request for an extraordinary circumstance exception on a case-by-case basis at our discretion. To the extent feasible, we also will review requests in conjunction with any similar requests made under other IPPS quality reporting and payment programs, such as the Hospital IQR Program and the Hospital VBP Program.

This policy would not preclude CMS from granting extraordinary circumstance exceptions to hospitals that do not request them if we determine at our discretion that a disaster or other extraordinary circumstance has affected an entire region or locale. If CMS makes such a determination to grant an extraordinary circumstance exception to hospitals in an affected region or locale, we will convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet Web site. This provision also aligns with the Hospital IQR Program's extraordinary circumstances extensions or exemptions policy.

We invited public comment on this proposal.

Comment: Many commenters supported the proposal to establish a request process for extraordinary circumstance exceptions for the Hospital Readmissions Reductions Program. The commenters noted that it was in alignment with other CMS hospital quality reporting programs and would provide relief to hospitals affected by a natural disaster or other extraordinary circumstances. Several commenters recommended that CMS develop a single extraordinary circumstance exception request form for all hospital quality reporting programs. Several commenters also supported the proposed hospital extraordinary circumstances waiver process, but requested additional information on the expected timeline for review of the submission and determination.

Response: We thank the commenters for their support, and note that we are expecting to update the extraordinary circumstances exception form currently in use by the other CMS quality reporting programs to include the Hospital Readmissions Reduction Program. The timeline for review and determination regarding requests for an extraordinary circumstance exception request can vary depending on a number of factors including the nature of the event, the exception requested, and the number of programs affected. We will work closely with hospitals who submit an extraordinary circumstance exception request to ensure that they receive a timely response.

Comment: Several commenters expressed concern that, because of the overlap in performance years, multiple payment years could be affected by the same loss of measure data. The commenters requested additional guidance regarding how a hospital should apply for an exemption if the period of affected data is used in performance periods for multiple payment years.

Response: We note that the extraordinary circumstance exception request form allows hospitals to list the quarter(s) that were affected by the extraordinary circumstance, and we are aware that the overlapping measure performance periods mean that extraordinary circumstance exception requests may impact multiple program years. We will work closely with an affected hospital to address these concerns.

Comment: Several commenters suggested that there are situations that do not prevent a hospital from submitting claims or other measure data in a timely fashion, but do cause performance to drop significantly for reasons outside of a hospital's control. The commenters suggested that circumstances outside the hospital's control may disrupt community services and hospital programs needed to continue readmission prevention efforts during natural disasters, which may result in higher readmission rates, and requested that the exceptions process be modified to recognize these situations. The commenters requested that CMS consider extraordinary circumstances on a case-by-case basis even when data submission is not inhibited, and that CMS allow for an appeals process governing extraordinary circumstance decisions.

Response: We thank the commenters for their recommendations. As we discussed in the proposed rule (80 FR 24497), based on our experience with the Hospital VBP Program and the Hospital IQR Program, we anticipate a need to provide exemptions only to a small number of hospitals where the ability to accurately or timely submits claims has been directly impacted. We will continue to monitor extraordinary circumstance exception requests to ensure that the process we are adopting in this final rule supports the goals of the Hospital Readmissions Reduction Program. However, we do not intend to modify the criteria for an extraordinary circumstance exception at this time. We do not anticipate a need to establish an appeals process for extraordinary circumstance exception determinations.

After consideration of the public comments we received, we are adopting the extraordinary circumstances exception policy as proposed.

F. Hospital Value-Based Purchasing (VBP) Program: Policy Changes for the FY 2018 Program Year and Subsequent Years

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 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 with comment period (78 FR 75120 through 75121); and the FY 2015 IPPS/LTCH PPS final rule with comment period (79 FR 50048 through 50087).

We have also codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2016 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 refer readers to that rule for further details.

Under section 1886(o)(7)(C)(iv) of the Act, the applicable percent for the FY 2016 program year is 1.75 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 2016 is $1,499,107,502, based on the December 2014 update of the FY 2014 MedPAR file. We intend to update this estimate for the FY 2016 IPPS/LTCH PPS final rule, using the March 2015 update of the FY 2014 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS) (77 FR 53573 through 53576). 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 2016, on a per-claim basis. We published proxy value-based incentive payment adjustment factors in Table 16 of the FY 2016 IPPS/LTCH PPS proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016–IPPS-Proposed-Rule-Home-Page-Items/FY2016–IPPS-Proposed-Rule-Tables.html*). The proxy factors are based on the TPSs from the FY 2015 program year. These FY 2015 performance scores are the most recently available performance scores that hospitals have been given the opportunity to review and correct. The slope of the linear exchange function used to calculate those proxy value-based incentive payment adjustment factors is 2.5797595162. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16.

We stated that we intended to update this table as Table 16A in this FY 2016 IPPS/LTCH PPS final rule (which will be available via the Internet on the CMS Web site) to reflect changes based on the March 2015 update to the FY 2014 MedPAR file. We also stated that we intended 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 2016 will continue to be based on historic FY 2015 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2016 program year until after this FY 2016 IPPS/LTCH PPS final rule is published. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2016, we will add Table 16B (which will be available via the Internet on the CMS Web site) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2016 program year. We expect that Table 16B will be posted on the CMS Web site in October 2015.

Comment: Several commenters urged CMS to make every effort to release the final VBP adjustment factors for FY 2016 as close to October 1, 2015 as possible. The commenters also requested that CMS review our timeline for reviewing these factors and make the necessary changes to ensure the final factors are released in a timely manner. In addition, the commenters expressed disappointment that CMS made no attempt to calculate FY 2016 proxy factors using the updated measures and domain weights finalized in last year's rule and believed that we should include an analysis of the FY 2016 impact in the proposed rule files that better aligns with the ever-changing program specifics and most recent data available.

Response: We appreciate the importance of timely release of the final adjustment factors for FY 2016, and while we are unable to guarantee an exact release date for the final factors, we will make every effort to release these factors in a timely fashion.

With regard to the FY 2016 proxy factors, while we understand commenters' concerns, we make these calculations using the most recently available performance data that hospitals have had the opportunity to review, which at the time of the final rule's publication does not include the scoring data for the next fiscal year. We do not believe it would be useful to publish proxy factors using domain weights finalized for the next fiscal year without the corresponding performance scoring data from the same program year because that action would mix policies between fiscal years, which is why we adopted the practice of calculating proxy factors from the previous year. We believe that these calculations represent the most accurate data available at the time of the final rule's publication and appropriately reflect policies for a single program year.

We also received a number of general comments on the Hospital VBP Program:

Comment: Several commenters expressed continued support for value-based payment models. Other commenters noted that the incentive structure could provide greater inducement for providers to work collaboratively to improve performance. One commenter applauded the Hospital VBP Program for assessing multiple

aspects of care as well as recognizing providers for both achievement versus national benchmarks and improvement versus baseline performance.

Response: We thank the commenters for their support.

Comment: Several commenters supported CMS' move away from clinical process measures and toward the use of outcome measures.

Response: We thank the commenters for their support.

Comment: One commenter commended CMS for providing advance notice of its policy proposals for the Hospital VBP Program structure and measures from FY 2017 to FY 2021.

Response: We thank the commenter for this support.

Comment: Several commenters appreciated CMS' continued attempts to better align with the Hospital IQR Program, Hospital Readmissions Reduction Program, the HAC Reduction Program, the Physician Value-Based Payment Modifier Program, and The Joint Commission to avoid redundancy and excessive resource burdens.

Response: We thank the commenters for their support.

Comment: One commenter supported the Hospital IQR Program as a mechanism for measure release and initial publication prior to inclusion into the Hospital VBP Program. The commenter believed this process allows the public and providers a ''preview year'' to better analyze and understand the methodology and impact of the measures as well as ensure accuracy of measurement and comparisons.

Response: We thank the commenter for this support.

Comment: Several commenters suggested specific means through which CMS could mitigate perceived biases within the Hospital VBP Program, including the addition of a measure that adjusts for small sample size, adjustments for provider penalties based on the sociodemographic status of their patient population, and the development of sociodemographic stratification measures built on factors used in analysis by key stakeholders.

Several commenters also suggested that CMS ensure the measures are appropriately validated and risk-adjusted by limiting performance-based payment programs to measures that have been endorsed by NQF and approved for specific program use by the MAP, a public-private partnership convened by the NQF for the purpose of providing input to the Secretary on the selection of certain quality and efficiency measures.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures. To date, we have found that hospitals that care for large proportions of patients of low sociodemographic status are capable of performing well on our measures (we refer readers to the 2014 Chartbook pages 48–57, 70–73, and 78 at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*).

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: One commenter recommended that CMS provide measure developers with direction about expectations regarding reporting periods, volume of procedure thresholds, and other critical elements of a measure to avoid compromising the integrity of the carefully designed and tested measures. This commenter believed that modified specifications subsequent to the testing process jeopardize the value of measure testing.

Response: We thank the commenter for this recommendation. Upon completion of measure testing, developers provide recommendations on reporting periods and minimum volume threshold based on reliability. We do not believe that we change measure specifications after testing in a way that would affect the validity of a measure.

Comment: One commenter raised concerns that the incentives and penalties are too insignificant to drive real change in quality and cost containment.

Response: As required by section 1886(o)(7)(B) of the Act, incentive payments will be funded for FY 2016 through a reduction to the FY 2016 base operating DRG payment for each discharge of 1.75 percent. The applicable percentage for FY 2017 and subsequent years is capped at 2 percent. This is the amount that we are statutorily authorized to withhold at this time.

Comment: Some commenters encouraged CMS to align objectives, measures, and reporting format for physician and hospital quality programs such as the Physician Value-Based Payment Modifier, EHR Incentive, and Hospital IQR Programs as well as the PQRS, and adopt a more streamlined and coordinated approach that will reduce what the commenters believed is unnecessary data collection and submission burden.

Response: As we stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626), we agree that alignment of incentives is an important goal, and we strive to align quality measurement and value-based purchasing efforts with the National Quality Strategy and across our programs, to the extent possible, given differences in payment system maturity and statutory authorities. We will continue to seek to align aspects of all of our quality initiatives to promote high quality care and continued innovation, as well as minimize burden on providers.

Comment: One commenter suggested that CMS ensure the measures hospitals are evaluated on are proven to actually improve patient outcomes and increase the quality of care for all patients.

Response: We agree with the commenter's suggestion and continue to work with stakeholders to define evidenced-based measures of quality that assess clinical care, patient experiences with care, and outcomes. We believe that the selected measures in the Hospital VBP Program are closely linked with improvements in quality of care and outcomes for all patients.

Comment: One commenter recommended that CMS develop a plan for incrementally phasing out

improvement scoring for specific measures, which have been included in the Hospital VBP Program for several consecutive years, as a means of emphasizing comparative achievement performance. The commenter added that such a plan would facilitate the development of properly structured incentives to drive the appropriate developments in healthcare delivery systems, resulting in better care for patients at a lower cost for payers.

Response: While we appreciate the commenter's goal of driving appropriate development in healthcare delivery systems, section 1886(o)(3)(B) of the Act requires that the performance standards with respect to measures adopted in the Hospital VBP Program include levels of achievement and improvement. As we have stated in the past (76 FR 26514), we believe improvement scores are an important incentive for many hospitals that participate in the Hospital VBP Program because improvement scores award points for showing improvement on measures, not solely for outperforming other hospitals.

Comment: One commenter expressed serious concerns regarding what the commenter believed to be the disproportionate effect of the Hospital VBP Program on teaching and large hospitals due to insufficient risk adjustment. The commenter noted that CMS has an obligation to ensure that measurement and comparisons are as accurate as possible.

Response: We are committed to accurate and fair hospital quality measurement comparison. We are currently analyzing how various hospitals are affected by the measures in the program. There is a statutorily required Hospital VBP Program monitoring and evaluation report to Congress due January 1, 2016, in which we expect to present our analysis of the Hospital VBP Program's impact on teaching and large hospitals.

Comment: One commenter recommended that CMS place a priority on ascertaining appropriate quality measures and encouraged CMS to include stakeholders that have relevant expertise in the measure development process.

Response: We are committed to defining appropriate, evidenced-based measures of quality. To the extent practicable, we continue to work with stakeholders, including those with relevant experience, and technical experts in the measure development process.

Comment: Several commenters expressed concern that CMS has not articulated a plan for calculating the Hospital VBP Program scores that will be affected by the transition from ICD–9–CM to ICD–10–CM/PCS codes and how such a transition could affect program measures and benchmarks, as well as the proposed baseline and performance periods. The commenters advised greater transparency and convening with stakeholders as a means of both soliciting feedback and addressing potential unintended consequences with respect to the transition. A few commenters requested that CMS elaborate on whether and how CMS will begin to re-specify claims-based measures in ICD–10–CM/PCS codes, given CMS' intent to use claims-based measures in future program years and in other quality measurement programs. Finally, one commenter urged CMS to oppose any Congressional efforts to further delay the scheduled implementation of ICD–10.

Response: We are aware of stakeholder concerns about the potential impacts to hospital performance on quality measures when ICD–10 is implemented on October 1, 2015, as well as calls for more extensive testing to understand the impacts before any payments or penalties are implicated. We are fully prepared to accept ICD–10-based claims data beginning October 1 for use in quality programs and ready to calculate measure results on schedule in accordance with established program timelines. We encourage stakeholders to subscribe to our listserv titled ''Hospital Inpatient Value-Based Purchasing (HVBP) and Improvement'' to receive notification of scheduled events. Stakeholders may join at *https://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic/ListServe/Register*.

Comment: One commenter noted that while CMS has updated the specifications for its chart-abstracted measures, CMS has not published any re-specification for the claims-based measures, specifically PSI–90.

Response: As with our chart abstracted measures, many claims-based measures have updated ICD–10 codes contained in the Measure Information Forms (MIFs) on the NQF Web site.[77] AHRQ's proposed changes for ICD–10–CM/PCS conversion of its quality indicators are available at: *http://www.qualityindicators.ahrq.gov/icd10/default.aspx*.

Comment: A few commenters requested that CMS convene a number of national provider calls to share how the ICD–10–CM/PCS transition may affect the measures, benchmarks, and performance standards and to solicit stakeholder feedback in preparation for FY 2017 rulemaking.

Response: We plan to convene national provider calls to share future plans for the ICD–10–CM/PCS transition. We encourage stakeholders to subscribe to our listserv titled ''Hospital Inpatient Value-Based Purchasing (HVBP) and Improvement'' to receive notification of scheduled events. Stakeholders may join at *https://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic/ListServe/Register*.

Comment: Several commenters expressed concern about the overlap of measures between the Hospital VBP Program and the HAC Reduction Program, given the different constructions and goals of each. These commenters urged CMS to use the measures in either the Hospital VBP Program or the HAC Reduction Program, but not both, to ensure the programs do not provide hospitals with conflicting signals or multiple payment penalties. One commenter expressed its preference that CMS remove the overlapping measures from the Hospital VBP Program, while another commenter recommended that CMS remove the overlapping measures from the HAC Reduction Program. One commenter added that CMS could explore a maximum penalty for a single measure across all pertinent programs.

Response: As we stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50056) in response to similar comments, we acknowledge that there is overlap in quality measures between the Hospital VBP Program and the HAC Reduction Program. While we are aware that commenters object to the possibility of scoring hospitals on certain measures under both programs, we note that these measures cover topics of critical importance to quality improvement in the inpatient hospital setting and to patient safety. We selected these quality measures because we believe 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. These measures track infections that could cause significant health risks to Medicare patients, and we believe it is appropriate to provide incentives for hospitals to avoid them under more than one program.

[77] MORT–30–AMI: NQF 0230 is available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=1286*.

MORT–30–HF: NQF 0229 is available at *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=1285*.

MORT–30–PN: NQF 0468 is available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=448*.

Hip/knee complications NQF 1550 is available at *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=1550*.

We further stress that the HAC Reduction Program and the Hospital VBP Program are separate programs with different purposes and policy goals. The HAC Reduction Program reduces payments to hospitals for excess HACs to increase patient safety in hospitals. On the other hand, the Hospital VBP Program is an incentive program that redistributes a portion of the Medicare payments made to hospitals based on their performance on various measures. Therefore, although the measures exist in more than one program, the measures are used and calculated for very distinct purposes. Accordingly, we believe that the critical importance of these measures to patient safety warrants their inclusion in both programs.

2. Retention, Removal, Expansion, and Updating of Quality Measures for the FY 2018 Program Year

a. Retention of Previously Adopted Hospital VBP Program Measures for the FY 2018 Program Year

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized our proposal to readopt measures from the prior program year for each successive program year, unless proposed and finalized otherwise (for example, if we propose and finalize the removal of a measure). We stated our belief that this policy would facilitate measure adoption for the Hospital VBP Program for future program years, as well as align the Hospital VBP Program with the Hospital IQR Program (77 FR 53592). In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24498), we did not propose to change our current policy of readopting measures from the prior program year for each successive program year.

We received several comments on measures we readopted into the FY 2018 program year:

Comment: One commenter noted its support for the policy CMS finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592) to readopt measures from prior program years each year unless otherwise indicated.

Response: We appreciate the commenter's support.

Comment: One commenter expressed support for the readoption of PSI–90 because it represents important patient safety outcomes for consumers and purchasers.

Response: We appreciate the commenter's support.

Comment: One commenter requested that CMS publish the PSI–90 methodology to be more transparent and reproducible.

Response: The methodology used to calculate the PSI–90 measure is detailed in the original technical report by the ARHQ Composite Workgroup: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/PSI_Composite_Development.pdf.*

Comment: One commenter expressed concern about the inclusion of the PSI–90 composite measure because it relies on claims-based data, which has limited clinical information, making it difficult for a claims-based measure to address nuances of comorbidities, severity, and complications and the ability to perform adequate risk-adjustment.

Response: While we acknowledge commenters' concerns about the use of claims-based data for the PSI–90 composite measure, we note that there are previously conducted validity studies that assess the relationship between administrative claim data and clinical information provided by medical records.[78] We also note that NQF reviewed the risk-adjustment methodology of the component indicators during its last cycle of NQF endorsement, and endorsed the PSI–90 composite measure as a valid and reliable.

Comment: One commenter did not support AHRQ's proposal as part of its NQF measure maintenance process to include PSI–10 in the PSI-composite given that the denominator is broad and a better indicator would require more than one measure.

Response: We appreciate commenter's concern and are aware that NQF is reviewing the PSI–90 composite with three additional components (PSI–9, PSI–10, and PSI–11), as part of the routine measure maintenance process. We will take NQF's decision on continuing endorsement into consideration for proposal in future program years under the Hospital VBP Program.

Comment: Several commenters did not support the inclusion of the PSI–12 component of the PSI–90 composite that is being readopted for the FY 2018 program year because it does not exclude trauma patients, given the high rates of Perioperative Pulmonary Embolism (PE)/Deep Vein Thrombosis (DVT) Rate in trauma patients. Without the trauma exclusion, commenters explained that facilities that treat a large amount of spinal cord injury patients and other traumatic cases will automatically be adversely affected and will not be able to compete with non-trauma facilities. Thus, commenters believe trauma centers are unfairly penalized by PSI–12. Some commenters suggested that the PSI–12 component also exclude patients with a diagnosis of cancer or brain tumors because these patients represent a very high-risk group due to their underlying medical condition.

Further, commenters suggested that PSI–12 relies on risk adjustment criteria that could lead to potential unintended consequences (for example, the measure could tag every LE thrombophlebitis, whether or not it is clinically significant, which could lead to useless data that will have little impact on quality). Finally, commenters noted that the PSI–12 component includes not otherwise specified (NOS) codes, including superficial thrombosis, which commenters did not believe is appropriate to measure because there are predictors of DVT that are outside of the control of the facility.

Response: We acknowledge commenters' concerns, but note that NQF reviewed the measure and took into account concerns about exclusions. NQF endorsed PSI–12 as a valid and reliable measure (NQF #0450) and as part of the PSI–90 composite measure during its last cycle of NQF endorsement (NQF #0531).

Comment: Several commenters expressed concern with the PSI–15 component of the PSI–90 composite measure that is being readopted for the FY 2018 program year because coding for accidental puncture is still non-uniform due to lack of clarity as to what constitutes an ''accident'' despite CMS' reference to the American Hospital Association Coding Clinical Guidance in the FY 2014 IPPS/LTCH PPS final rule. The commenters stated that punctures or lacerations are often incorrectly coded as ''accidental'' when the puncture or laceration was part of the surgery. Commenters requested that CMS provide more precise guidance regarding the correct coding of the PSI–15 component of the PSI–90 measure to minimize confusion and improve the accuracy of the measure.

Response: We acknowledge commenters' specific concerns regarding coding of the PSI–15 component of the PSI–90 composite. We continue to believe that the American Hospital Association Coding Clinical Guidance provides sufficient guidance regarding the correct coding of

[78] Sadeghi B, White RH, Maynard G, Zrelak P, Strater A, Hensley L, Cerese J, Romano PS. Improved coding of postoperative deep vein thrombosis and pulmonary embolism in administrative data (AHRQ patient safety indicator 12) after introduction of new ICD–9–CM diagnosis codes. Medical care. 2015;53(5): e37–e40; Sadeghi B, Baron R, Zrelak P, Utter GH, Geppert JJ, Tancredi DJ, Romano PS. Cases of iatrogenic pneumothorax can be identified from ICD–9–CM coded data. American Journal of Medical Quality, 2010;25(3), 218–224.

''accidental'' punctures and lacerations that are not ''intrinsic'' or ''inherent'' in a major procedure. We believe that hospitals should continue to provide education to their staff on correct coding of PSI–15. The AHRQ Quality Improvement Toolkit may also provide additional guidance to facilitate improvements to documentation and coding: *http://www.ahrq.gov/professionals/systems/hospital/qitoolkit/b4_documentationcoding.pdf*.

Comment: One commenter recommended that CMS separate public safety measures, such as PSI–03 Pressure Ulcer Rate and PSI–15 Accidental Puncture or Laceration to increase transparency for consumers and providers.

Response: We thank the commenter for this suggestion and we will take it into consideration in future rulemaking.

Comment: One commenter expressed continued concern about including PSI–9, PSI–10, and PSI–11 in the PSI–90 composite because of concerns with the measures' validity. The commenter believed that improvements in PSI performance reflect ''gaming'' of the system and not necessarily safer care for patients. The commenter recommended that CMS implement key steps to improve the validity of these claims-based measures and referred to similar comments which it made in the context of the Hospital IQR Program in section VIII.A.1.b. of the preamble of this final rule.

Response: We appreciate the commenter's concern and are aware that NQF is reviewing the PSI–90 composite with three additional components (PSI–9, PSI–10, and PSI–11), as part of the routine measure maintenance process. We will take NQF's decision on continuing endorsement into consideration when evaluating whether the measure remains appropriate for the Hospital VBP Program. Regarding the commenter's concerns regarding the validity of the PSI–90 composite, we note that NQF has previously endorsed the PSI–90 composite as a valid measure (NQF #0531). We continue to believe the PSI–90 composite is an important measure of patient safety.

Comment: One commenter noted that since PSI–7 and NHSN CLABSI are both in the Hospital VBP Program, central line infections are counted twice (first as part of PSI–90 and then again as a NHSN CLABSI outcome measure) with different data sources. Commenter recommended the use of the NHSN CLABSI measure because it draws from clinical data and continues to have concerns with the PSI–90 measure.

Response: While we acknowledge that there is the potential for overlap between the two measures, the source of the data is different. PSI–7 is based on coding of physician documentation and does not account for vascular catheter exposure, whereas the CLABSI measure relies on microbiologic laboratory confirmation and does account for vascular catheter exposure (catheter days). Despite the potential for some overlap in these measures, we continue to believe that both measures are important to reducing central line associated blood stream infections.

Comment: A few commenters expressed concern with readopting the MSPB–1 measure because it measures volume of spending without considering quality or appropriateness of care. The commenters noted that it might create incentives for hospitals to reduce utilization of appropriate and necessary diagnostic technologies and therapeutic options. The commenters believed the measure lacks sufficient granularity and relies on poor risk-adjustment and attribution methodologies.

Response: We finalized the MSPB–1 measure for inclusion in the Hospital VBP Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), where we addressed a number of concerns related to the measure. With regard to linking MSPB–1 to quality of care, we have emphasized that within the Hospital VBP program, MSPB–1 is combined with other quality measures in order to calculate the TPS (77 FR 53586). We continue to believe that the method of calculating a hospital's TPS, which ensures that the MSPB–1 is only a portion of the TPS, incentivizes hospitals to continue to provide high quality care. We further note that the measure is risk-adjusted using a methodology that is consistent with the risk-adjustment model used for several CMS initiatives.

Comment: One commenter recommended that in order to most accurately and reliably report meaningful colon and abdominal hysterectomy SSI rates, exenterations be excluded from the measure. The commenter believed that CMS disproportionately skews and penalizes large tertiary centers that perform exenterations, especially for recurrent cancers.

Response: We agree that not all surgical procedures confer the same risk for SSI, and some surgical patients are at greater risk for infection because their functional status is compromised by disease conditions or other patient-specific factors. CDC is collecting additional SSI risk factors that will enable new risk modeling using the 2015 SSI data. While these new risk models can take into account additional factors that place patients at risk for infection, not all SSI risk differences associated with procedural and patient differences can be included because of the data collection burden that would be imposed on NHSN users.

Comment: One commenter did not support the THA/TKA measure CMS finalized for the FY 2019 program year because of validity and appropriateness concerns. The commenter questioned the accuracy of the administrative data sets for both procedures. The commenter also noted that despite NQF's endorsement of sociodemographic risk adjustment refinements, this measure is not risk-adjusted for sociodemographic factors, which have significant correlation with variability of outcomes. The commenter also noted the current composition of the measure could result in problems with access to total joint surgery for certain classes of patients (for example, obese, lupus patients and transplant patients) given that they carry a higher risk for complications.

Response: We acknowledge the commenter's concerns regarding the use of administrative data for the THA/TKA measure, but note that there are previously conducted validation studies that validate the use of administrative claims data to provide sufficient clinical information.[79] We believe that the current composition of the THA/TKA measure will not result in decreased patient access to THA/TKA procedures, as the measure incorporates an appropriately comprehensive risk-adjustment methodology for patient case-mix and comorbidity.

As we discussed more fully above, while we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures. To date, we have found that hospitals that care for large proportions of patients of low sociodemographic status are capable of performing well on our measures (we

[79] Grosso LM, Curtis JP, Lin Z, et al. Hospital-level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA): Measure Methodology Report. June 2012. Available at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

refer readers to the 2014 Chartbook pages 48–57, 70–73, and 78 at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*).

Comment: One commenter did not support CMS' inclusion of the PC–01 measure because it is Web-based and there has not been any chart validation for accuracy and consistency of data collection across hospitals. Further, the commenter believed the benchmark of 0 percent is unrealistic because The Joint Commission has stated that not all justifications for an elective delivery are included on the ICD–9–CM Justification Table.

Response: We acknowledge commenter's concern regarding the PC–01 measure, but note that PC–01 is NQF-endorsed (NQF #0469) as clinically valid. Moreover, we disagree with the assertion that the benchmark of 0 percent is unrealistic because not all justifications for an elective delivery are included in the ICD–9–CM Justification Table. As we have previously noted, the benchmark is intended to represent a level of excellent performance to which hospitals generally should aspire. While no measure can account for every possible situation, the measure specifications (available at: *https://manual.jointcommission.org/releases/TJC2015A1/MIF0166.html*) provide a large number of ICD–9–CM Principal Diagnosis Code or Other Diagnosis Codes for conditions possibly justifying elective delivery prior to 39 weeks gestation. Furthermore, the 0 percent benchmark for PC–01 was calculated from the mean of the top 10 percent for all hospitals during the baseline period. We continue to believe that hospitals should aspire to prevent elective deliveries from being performed before the gestational age of 39 weeks without a medical indication.

Comment: One commenter recommended that CMS retire measures when the evidentiary basis for a measure has changed, the cost of collection and measurement burden outweighs the utility of the measure, or the measure has demonstrated minimal impact on health outcomes and status.

Response: We thank the commenter for these suggestions and we will take these comments into consideration in future rulemaking.

Comment: One commenter asked that CMS suspend use of HCAHPS measures addressing pain management until the revised questions are reexamined to determine whether they are contributing to overprescribing due to the pressures HCAHPS scores place on providers.

Response: We understand and share the commenter's concerns about inappropriate prescribing of prescription opioids and its link to prescription opioid dependence, abuse, and addiction. We believe that the rising level of opioid dependence, abuse, addiction, and overdose is a public health emergency in the United States. Although we are not aware of scientific research that establishes a causal connection between HCAHPS scores and provider prescription practices, we recognize that there have been anecdotal reports suggesting a link and that many providers believe such a link exists. However, there is no evidence of which we are aware that finds failing to prescribe unneeded pain medications lowers a hospital's HCAHPS scores.

There are three questions on the HCAHPS survey which directly address the issue of pain control during a patient's hospital stay. Recent studies have shown a positive relationship between patients being satisfied with their pain relief while in the hospital (that is, giving high scores on pain control questions) and decreased chronic opioid use.[80]

There is evidence that good physician and nurse communication are the strongest predictors of better patient experience survey scores, including HCAHPS scores.[81] Finally, the 2018 HCAHPS questions will include the Care Transition Management measure which will place additional focus on educating patients about their outpatient care plan. We believe that this additional measure will further highlight patient safety and outpatient care coordination.

Comment: One commenter suggested that CMS evaluate an adjustment to the HCAHPS survey based on a secondary psychiatric diagnosis because these patients report significantly lower scores on the Communication with Nurses, Communication with Doctors, and Pain Management HCAHPS survey dimensions. The commenter suggested that the investigation could address hospital concerns related to pain management and opioid abuse and could identify the percentage of patients a hospital is treating who suffer from opioid addiction and adjust the data accordingly without adding substantial administrative burden to hospitals.

Response: Currently, we do not collect or investigate secondary psychiatric diagnoses for HCAHPS. We do collect and measure self-rated mental health which is correlated with such diagnoses.[82] Findings have shown that self-rated mental health is not strongly associated with HCAHPS scores after controlling for the full set of current HCAHPS patient-mix adjustment (PMA) variables. It is unlikely that secondary psychiatric diagnoses would be an important addition to HCAHPS PMA, even if there is a bivariate association with HCAHPS scores.

With respect to opioid abuse, recent studies have shown a positive relationship between patients being satisfied with their pain relief in the hospital and decreased chronic opioid use.[83] There is evidence that, in general, good physician and nurse communication are the strongest predictors of better patient experience survey scores, including HCAHPS scores.[84]

Comment: One commenter suggested that CMS separate the Hospital Cleanliness & Quietness dimension from the rest of the HCAHPS Survey because these two elements are separated in the HCAHPS data that is reported in *Hospital Compare* and it would be useful for consumers to know which element is driving the performance and improvement within these quality areas. The commenter noted that hospital cleanliness is especially important to hospital environmental services members. Another commenter recommended that Hospital Cleanliness be weighted more heavily than Hospital Quietness for the dimension score because hospital cleanliness has a direct impact on the prevention of hospital-acquired conditions.

Response: On *Hospital Compare,* we provide separate scores for hospital cleanliness and hospital quietness. These separate scores are available to consumers to use in choosing a hospital. In presenting a composite clean/quiet dimension score in the Hospital VBP Program, there is no objective rationale for giving undue weight to one or the

[80] Maher DP, Wong W, Woo P, et al., ''Perioperative Factors Associated with HCAHPS Response of 2,758 Surgical Patients.'' *Pain Medicine,* 2014; Nota SPFT, Spit SA, Voskuyl T, et al., ''Opioid use, satisfaction and pain intensity after orthopedic surgery.'' *Psychosomatics,* 2015.

[81] Elliott MN, Kanouse DE, et al., ''Components of Care Vary in Importance for Overall Patient Reported Experience by Type of Hospitalization.'' *Medical Care,* 2009.

[82] Ahmad F, Jhajj AK, Stewart DE, et al., ''Single item measures of self-rated mental health: a scoping review.'' *BMC Health Services Research,* 2014; Kim G, DeCoster J, Chiriboga, DA, et al., ''Association between self-rated mental health and psychiatric disorders among older adults: do racial/ethnic differences exist?'' *American Journal of Geriatric Psychiatry,* 2011.

[83] Maher DP, Wong W, Woo P, et al., ''Perioperative Factors Associated with HCAHPS Response of 2,758 Surgical Patients.'' *Pain Medicine,* 2014; Nota SPFT, Spit SA, Voskuyl T, et al., ''Opioid use, satisfaction and pain intensity after orthopedic surgery.'' *Psychosomatics,* 2015.

[84] Elliott et al., Medical Care, 2009.

other dimension since both hospital cleanliness and quietness are observed to impact patient recovery.

Comment: Several commenters expressed concern for the sufficiency of the risk adjustment of the HCAHPS composite measures and believe that the methods for delivering the survey are outdated given the shift to Web-based activities and suggested that CMS conduct research to improve the delivery methods of the HCAHPS survey.

Response: While Web-based surveys are increasing in use and have much value in other contexts, a recent Randomized Control Trial (RCT) study found Web-based approaches currently result in lower response rates and poorer representativeness than any of the four approved HCAHPS modes in the HCAHPS population.[85] We will continue to explore this option as hospital email address information on patients becomes more complete and daily Internet access becomes more complete in the HCAHPS target population.

Comment: Two commenters stated that patient satisfaction does not lead to better health outcomes and therefore using HCAHPS as a measure may not be driving positive outcomes. One commenter urged CMS to work with AHRQ to assess patient satisfaction's impact on health outcomes.

Response: HCAHPS measures patient experience, a dimension of quality care that is distinct from clinical measures of quality and of inherent value. Improving all aspects of quality of care, including patient experience, is a CMS and HHS policy priority. Recent reviews have found that the vast majority of studies have found positive associations between patient experience and clinical process measures of quality, outcomes, and efficiency, particularly in the inpatient setting.[86] The most widely cited article that found negative associations, by Fenton et al., has been identified as being methodologically flawed in a recent reanalysis of its data.[87]

b. Removal of Two Measures

One consideration in determining whether a measure should be retained or removed from the program is based on an analysis of whether the measure is ''topped-out.'' We have adopted two criteria for determining the ''topped-out'' status of Hospital VBP measures:

- Statistically indistinguishable performance at the 75th and 90th percentiles; and
- Truncated coefficient of variation ≤ 0.10.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24498 through 24500), we proposed to remove the IMM–2: Influenza Immunization and AMI–7a: Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival measures, effective for the FY 2018 program year. We believe that removing these measures will continue to ensure that we make valid statistical comparisons through our finalized scoring methodology, while reducing the reporting burden on participating hospitals.

(1) Removal of IMM–2: Influenza Immunization Measure

Based on our evaluation of the most recently available data, we believe that IMM–2 is ''topped-out.'' As we have discussed in prior rulemaking, measuring hospital performance on ''topped-out'' measures will have no meaningful effect on a hospital's TPS, given that performance on ''topped-out'' measures is generally so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

As discussed further in section VIII.A.3.b. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24557 through 24558) and this final rule, we believe that this measure should continue to be part of the Hospital IQR Program measure set because it is the only measure that addresses the Best Practices to Enable Healthy Living goal in the CMS Quality Strategy and priority of the same name in the National Quality Strategy.

We invited public comment on this proposal.

Comment: Most commenters supported the proposal to remove the IMM–2 measure because it is ''topped-out.''

Response: We thank the commenters for their support.

Comment: A few commenters did not support the proposal to remove IMM–2 from the Hospital VBP Program despite its ''topped-out'' status. One commenter believed that the measure will ensure that providers continue to administer this vaccine, and given that adult immunization rates remain low, the commenter noted that quality measures are an important tool to increase vaccination rates. Another commenter did not believe that CMS' measure removal criteria are patient-centered. This commenter noted that a measure might meet the criteria for removal but a large number of patients may still fail to receive the appropriate standard of care.

Response: We disagree with the commenter that the measure removal criteria for IMM–2 are not patient-centered. We continue to believe that influenza immunization is important; hence, we have opted to retain the measure in the Hospital IQR Program. However, as discussed in prior rulemaking, measuring hospital performance on ''topped-out'' measures has no meaningful effect on a hospital's TPS, given that meaningful distinctions in performance between hospitals cannot be made. As we have stated in the past (76 FR 26500), we believe that if a measure is ''topped-out,'' then there is no room for improvement for the vast majority of hospitals.

After consideration of the public comments we received, we are finalizing the proposal to remove IMM–2 from the FY 2018 program year and subsequent years. (2) Removal of AMI–7a: Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival Measure.

Our evaluation of the most recently available data shows that AMI–7a is not widely reported by hospitals, and that many hospitals have less than the minimum number of cases required for reporting because most acute myocardial infarction patients receive percutaneous coronary intervention instead of fibrinolytic therapy. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24499), we proposed to remove AMI–7a because collection of the measure data is burdensome to hospitals and measure data are infrequently reported. Therefore, we do not believe that its continued adoption under the Hospital VBP Program will advance our quality improvement goals. As discussed in section VIII.A.3.b. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24558 through 24559), we also proposed to remove the chart-abstracted version of

[85] Elliott MN, Brown J, Lehrman WG, Beckett MK, Hambarsoomian K, Giordano L, Goldstein E.: ''A Randomized Experiment Investigating the Suitability of Speech-Enabled IVR and Web Modes for Publicly Reported Surveys of Patient' Experience of Hospital Care.'' *Medical Care Research and Review,* 2013.

[86] Anhang Price R, Elliott MN, Cleary PD, Zaslavsky AM, Hays RD: ''Should Health Care Providers be Accountable for Patients' Care Experiences?'' *Journal of General Internal Medicine,* 2014a; Anhang-Price R, Elliott MN, Zaslavsky AM, Hays RD, Lehrman WG, Rybowski L, Edgman Levitan S, Cleary PD: ''Examining the Role of Patient Experience Surveys in Measuring Health Care Quality'' *MCRR,* 2014b.

[87] Xu X, Buta E, Anhang-Price R, Elliott MN, Hays RD, Cleary PD. (2014). ''Methodological Considerations when Studying the Association between Patient-Reported Care Experiences and Mortality'' *Health Services Research,* 2014.

AMI–7a, but to retain the electronic version for the CY 2016/FY 2018 payment determination and subsequent years under the Hospital IQR Program.

We invited public comment on this proposal.

Comment: Most commenters supported the proposal to remove the AMI–7a measure. Some commenters noted that the measure will not advance quality improvement goals, that data collection is burdensome, and that it no longer reflects current clinical guidelines and standards of care. Some commenters also agreed that many hospitals would have a difficult time achieving the minimum number of cases needed to report this measure.

Response: We thank the commenters for their support of removal. While we acknowledge that primary percutaneous coronary intervention (PCI) remains the recommended method of reperfusion when it can be performed in a timely fashion by experienced practitioners, we do not agree that this measure no longer reflects current clinical guidelines.

Comment: One commenter recommended that CMS establish a system to periodically monitor performance on retired measures to ensure that quality gains are sustained.

Response: At this time, we do not have a formal mechanism in place to monitor whether measures that have been ''topped-out'' remain ''topped-out.'' However, we monitor the performance of removed measures to ensure that performance does not decline significantly and will continue to do so. We must balance the costs of continued monitoring of a successful measure with high levels of performance with the adoption of other measures where there are opportunities for improvement in clinical quality. We will take the recommendation into consideration in the future. For now, we continue to believe that if a measure is ''topped-out,'' there is no room for improvement for the vast majority of hospitals, and that measuring hospital performance on that measure will not have a meaningful effect on a hospital's TPS.

Comment: One commenter did not support the removal of the AMI–7a measure because the commenter did not believe the measure removal criteria are patient-centered. The commenter noted that a measure might meet the criteria for removal but a large number of patients may still fail to receive the appropriate standard of care.

Response: We disagree with the commenter that our measure removal criteria are not patient-centered. Currently, most acute myocardial infarction patients receive percutaneous coronary intervention instead of fibrinolytic therapy. While we acknowledge commenter's concern, our evaluation data shows that AMI–7a is infrequently reported, and in consequence, does not result in better patient outcomes for the AMI population. Furthermore, we have no reason to believe that removal of the measure will decrease the use of fibrinolytic therapy for those who need it.

After consideration of the public comments we received, we are finalizing the proposal to remove AMI–7a from the Hospital VBP Program for the FY 2018 program year and subsequent years.

c. New Measure for the FY 2018 Program Year: 3-Item Care Transition Measure (CTM–3) (NQF #0228)

We consider measures for adoption based on the statutory requirements, including specification under the Hospital IQR Program, posting dates on the *Hospital Compare* Web site, and our priorities for quality improvement as outlined in the CMS Quality Strategy, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf*.

The 3-Item Care Transition Measure (CTM–3) is an NQF-endorsed measure. We adopted this measure in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53513 through 53516). Initial measure data were posted on *Hospital Compare* in December 2014 and the full measure specifications are available at: *http://www.caretransitions.org/documents/CTM3Specs0807.pdf*. Specifications for the Care Transition Measure as used in the HCAHPS Survey can be found in the current HCAHPS Quality Assurance Guidelines, *http://www.hcahpsonline.org/qaguidelines.aspx*.

The CTM–3 measure adds three questions to the HCAHPS Survey, as follows:

- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
- When I left the hospital, I clearly understood the purpose for taking each of my medications.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
  - ☐ I was not given any medication when I left the hospital

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50065 through 50066), we stated that we were considering proposing to add the CTM–3 measure from the HCAHPS Survey to the Patient and Caregiver Centered Experience of Care/Care Coordination (PCCEC/CC) domain of the FY 2018 program year, and we sought public comments on this topic. We specifically sought public comments on how the new CTM–3 dimension should be included in the scoring methodology that we have adopted for the PCCEC/CC domain.

Based on other public comments last year, we agreed to release additional information about the validity, reliability, and statistical properties of the CTM–3 measure when we proposed the measure (79 FR 50066). We made this information publicly available in 2014 through the NQF re-endorsement process of the HCAHPS Survey (NQF #0166), available at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867*.

We note that the MAP supported the inclusion of the CTM–3 measure in the Hospital VBP Program in its MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, available at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*. The MAP noted that the addition of the CTM–3 measure will fill a gap in measuring care transitions.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24499), we proposed this measure for the Hospital VBP Program based on the MAP recommendation, our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least 1 year before the beginning of the performance period for that measure. We believe that the proposed addition of the CTM–3 measure to the Hospital VBP Program meets the statutory requirements for inclusion in the FY 2018 program year. Finally, we also believe that this measure, in conjunction with the HCAHPS survey, assesses an important component of quality in the acute care inpatient hospital setting. However, we emphasize that HCAHPS scores are designed and intended for use at the

hospital level. We do not endorse the use of HCAHPS scores for comparisons within hospitals, such as comparison of HCAHPS scores associated with a particular ward, floor, provider, or nursing staff. Further, the pain domain questions are intended to evaluate patients' experience of their pain management. HCAHPS pain domain results are not designed to judge, or compare, appropriate versus inappropriate provider prescribing behavior.

We invited public comment on this proposal.

Comment: Several commenters supported the proposed adoption of the CTM–3 measure as a good measure of hospital communication and care, citing that the inclusion of the measure would not only address all aspects of a defined episode of care but it would also affect the appropriate administration of prescribed antimicrobials, contribute to the early recognition of post-discharge infections, and incentivize hospitals to improve their coordination of patient transitions to outpatient care settings. These commenters noted that CTM–3 also features the necessary components to assess the quality of care received by patients at discharge, patient-caregiver comprehension of assigned health management plans, and the distribution of appropriate treatment, collectively mitigating the current rates of hospital readmissions and mortality among Medicare recipients.

Response: We thank the commenters for their support.

Comment: One commenter expressed appreciation for CMS' continued review of the HCAHPS patient-mix adjustment, and applauded CMS' more granular approach to adjust based on the language spoken by the patient.

Response: We thank the commenter for this support.

Comment: Several commenters expressed support for the measure, but noted concern with regard to its potential effect on the PCCEC/CC domain, the length and burdensome nature of the HCAHPS survey, as well as potential issues with patient comprehension of the language used in the questions. The commenters questioned the validity of the HCAHPS tool, given that this voluntary survey already has a low response rate.

Some commenters suggested that CMS should consider using a threshold (such as percentiles) rather than a consistency score to ensure that this new measure does not adversely affect the HCAHPS domain. Several commenters recommended CMS decrease the HCAHPS consistency score to 10 percent and weight the HCAHPS measure total score with the CTM–3 measure at 90 percent. Another commenter recommended revising the methodology of the consistency score to more accurately measure consistent performance and retaining the 20 percent score. Instead, this commenter suggested using the HCAHPS floor values as the minimum range for consistency, and that CMS could use the 25th percentile value. The commenter stated that, in this way, consistency points would only be rewarding hospitals that maintain a reasonable level of performance in each HCAHPS measure.

Response: The CTM–3 measure is an established and validated measure of patient experience with care transitions that has been incorporated into the HCAHPS measure. The measure was developed by Eric Coleman, MD, MPH, Professor of Medicine and Health at the Division of Health and Policy Research at the University of Colorado Anschutz Medical Campus. Dr. Coleman is the founder and director of The Care Transitions Program (*www.caretransitions.org*). The three Care Transition Measure questions are under copyright of The Care Transitions Program. We conducted additional analyses for HCAHPS and released additional information about the validity, reliability, and statistical properties of the CTM–3 measure when we proposed the measure (79 FR 50066). We made this information publicly available in 2014 through the NQF re-endorsement process of the HCAHPS Survey (NQF #0166), available at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867*.

With respect to response rates and burden of the HCAHPS survey, available evidence suggests the addition of 3 items has no measurable effect on response rates. National HCAHPS response rates are unchanged to the nearest percentage point over the last four years. A 2008 meta-analysis found response rates are only weakly associated with non-response bias in probability sample surveys similar to HCAHPS, surveys that also adhere to high process standards of survey methodology.[88]

As indicated by the formula, consistency points only reward performance that is consistently good across the HCAHPS dimensions. Consistently poor performance does not earn consistency points. Consistency points provide additional incentives beyond achievement and improvement points to improve a hospital's lowest-performing dimension. Adding the CTM measure to the HCAHPS performance score should not adversely affect consistency point scoring. In particular, the score for this measure for the purposes of consistency points is compared to all other hospitals in the baseline period. A hospital will be awarded the maximum 20 consistency points when its performance on each HCAHPS dimension during the performance period equals or exceeds each dimension's achievement threshold. Otherwise, if any dimension rate is less than the achievement threshold, consistency points are awarded based on the lowest dimension's location relative to the worst performing hospital on that dimension. Evaluations have found that consistency points have good psychometric properties and positively correlate with overall HCAHPS performance.

Comment: One commenter suggested that CMS should provide further discussion and instruction to hospitals regarding the implementation of the proposed 3-Item Care Transition Measure and whether this new measure will align with the existing measures in the HCAHPS survey. Another commenter did not support the inclusion of the CTM–3 measure because the commenter believed the survey results are subjective, the results inaccurately reflect the effectiveness of hospitals' care transitions, and the survey does not assess post-discharge planning efforts via Web-based patient portals and outcomes.

Response: The HCAHPS survey and its administrative protocols are designed to produce standardized information about patient's perspectives of care that allow objective and meaningful comparisons of hospitals on topics that are important to consumers. All survey vendors as well as hospitals which self-administer the HCAHPS survey receive annual training and oversight on HCAHPS survey implementation. The CTM–3 measure added 3 questions to the HCAHPS questionnaire in 2013. Survey vendors and self-administering hospitals have had two years of experience collecting data for the three HCAHPS questions (listed above) which comprise the CTM–3 measure. We have conducted additional analyses for HCAHPS, with results available as part of the HCAHPS NQF submission, confirming this measures' reliability and validity in the HCAHPS population (*http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867*).

Comment: One commenter expressed concern that the CTM–3 measure does

[88] Groves RM, Peytcheva E: ''The Impact of Nonresponse Rates on Nonresponse Bias: A Meta Analysis.'' *Public Opinion Quarterly,* 2008.

not fully ensure medication therapy in the continuity of care for patients with acute coronary syndrome (ACS) and chronic obstructive pulmonary disease (COPD) in particular. The commenter suggested that CMS take additional steps to close these gaps via proper medication management, adding a question asking patients to assess their ease of obtaining prescription immediately after discharge, and updating the medication-related question to: ''When I left the hospital, I clearly understood the purpose for taking each of my medications and how long I should take each of my medications.''

Response: The HCAHPS Survey is a standardized survey instrument and data collection methodology for measuring patients' experience of hospital care. The HCAHPS survey produces comparable nation-wide data which allow consumers to make objective and meaningful comparisons of hospitals thus supporting consumer choice of hospital. The emphasis is on the patients' experience of care while in the inpatient setting. Any modification of the HCAHPS Survey needs to focus on care provided by the hospital. We will share the commenter's question suggestions to the CTM–3 measure developers. Further, HCAHPS survey results are publicly reported to create incentives for hospitals to improve the quality of care they provide in their facilities.

Comment: One commenter recommended that CMS consider alternative approaches to documenting the CTM–3 measure, including the use of emails and Web-based portals, which, the commenter believed, would make data collection and aggregation less costly and therefore allow hospitals to gather a larger sample size of data.

Response: While Web-based surveys are increasing in use and have much value in other contexts, a recent Randomized Control Trial (RCT) study found Web-based approaches currently result in lower response rates and poorer representativeness than any of the four approved HCAHPS modes in the HCAHPS population.[89] We will continue to explore Web-based approaches as hospital email address information on patients becomes more complete and as daily internet access becomes more complete in the HCAHPS target population.

Comment: Several commenters requested that CMS implement the CTM–3 measure sooner than the FY 2018 program year.

Response: We are unable to implement the measure sooner than the FY 2018 program year. First, in accordance with section 1886(o)(2)(C)(i) of the Act, we post data on measures on *Hospital Compare* for at least one year before we select them for the Hospital VBP Program. CTM–3 initial measure data was posted on *Hospital Compare* in December 2014. Further, under section 1886(o)(3)(C) of the Act, we establish and announce the performance standards for all measures in the Hospital VBP Program at least 60 days before the beginning of the performance period. As discussed below, we are finalizing the baseline period for the CTM–3 measure as January 1, 2014—December 31, 2014 and the performance period as January 1, 2016—December 31, 2016.

After consideration of the public comments we received, we are finalizing the proposal to add CTM–3 to the FY 2018 program year and subsequent years.

d. Removal of Clinical Care—Process Subdomain for the FY 2018 Program Year and Subsequent Years

We have previously adopted three measures for the Clinical Care—Process subdomain for the FY 2017 program year (for example, 79 FR 50062 (Table on Previously Adopted and New Measures for the FY 2017 program year)). However, as proposed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24499), we are finalizing our proposal to remove the AMI–7a and IMM–2 measures from the Hospital VBP Program, and we did not propose to adopt any additional measures for the Clinical Care—Process subdomain. Because only one measure, PC–01 Elective Delivery, which measures the incidence of elective births prior to 39 weeks gestation, would remain in the Clinical Care—Process subdomain for the FY 2018 program year, we proposed to move PC–01 to the Safety domain and to remove the Clinical Care—Process subdomain beginning with the FY 2018 program year.

As we have stated over the past several years (for example, 79 FR 50084), we desire the Hospital VBP Program to be as inclusive as possible while maintaining and ensuring the reliability of the domains. We believe that the PC–01 Elective Delivery measure continues to be appropriate for the Hospital VBP Program because, in 2012, nearly one million Medicare beneficiaries were women age 45 and under.[90] Further, in 2011, Medicare paid for roughly 14,000 births (79 FR 50060). However, not all hospitals provide maternity services, which would leave these hospitals with no Clinical Care-Process subdomain measures to report in FY 2018 if PC–01 remains the only measure in that subdomain.

We believe that the PC–01 Elective Delivery measure, currently in the Clinical Care—Process subdomain, can appropriately be recategorized as a Safety domain measure. PC–01 addresses a process designed to reduce risk to both the neonate and the mother, thereby making care safer. Guidelines from the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics state elective deliveries should not be performed at <39 weeks gestation unless medically indicated.[91] Evidence has shown that early-term deliveries result in significant short-term neonatal mortality and result in more cesarean deliveries, and longer maternal length of stay.[92] Furthermore, the MAP Hospital Workgroup has included PC–01 as an ''obstetrical adverse event'' measure in its Safety family of measures.[93] As we continue to align our measure categorizations more closely with the CMS Quality Strategy, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24500), we proposed to recategorize PC–01 as a Safety measure in the Safety domain, and for the reasons discussed above, to remove the Clinical Care—Process subdomain beginning with the FY 2018 program year.

Finally, we proposed that if we finalize our proposal to remove the Clinical Care—Process subdomain, we would rename the Clinical Care—Outcomes subdomain as simply the Clinical Care domain. We also proposed to reweight the domains to reflect our proposals, which we detail in section

[89] Elliott MN, Brown J, Lehrman WG, Beckett MK, Hambarsoomian K, Giordano L, Goldstein E.: ''A Randomized Experiment Investigating the Suitability of Speech-Enabled IVR and Web Modes for Publicly Reported Surveys of Patient' Experience of Hospital Care.'' *Medical Care Research and Review,* 2013.

[90] Centers for Medicare & Medicaid Services. (2013). Table I.3—Medicare Enrollment/ Demographics. Available at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/CMS_Stats_2013_final.pdf.*

[91] Clark, S., Miller, D., Belfort, M., Dildy, G., Frye, D., & Meyers, J. (2009). Neonatal and maternal outcomes associated with elective delivery. [Electronic Version]. *Am J Obstet Gynecol.* 200:156.e1–156.e4.

[92] Glantz, J. (Apr.2005). Elective induction vs. spontaneous labor associations and outcomes. [Electronic Version]. *J Reprod Med.* 50(4):235–40. Available at: *http://www.researchgate.net/publication/7826004_Elective_induction_vs._spontaneous_labor_associations_and_outcomes.*

[93] MAP Families of Measures: Safety, Care Coordination, Cardiovascular Conditions, Diabetes Final Report, October 2012, p. 46.

IV.G.8.a. (erroneously referenced as section IV.G.7.a. in the preamble of the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24508 through 24509).

We invited public comments on these proposals.

Comment: Several commenters supported the proposal to remove the Clinical Care—Process subdomain and move the PC–01 measure to the Safety domain beginning with the FY 2018 program year.

Response: We thank the commenters for their support.

Comment: Several commenters expressed confusion regarding the inclusion of process measures in future program years. These commenters recommended that CMS retain the Clinical Care—Process subdomain at a weight of zero and work to repopulate this domain with appropriate process of care measures for future years when the domain weight could be adjusted. One commenter explained that many hospitals would only qualify for the Hospital VBP Program because they meet case minimums for process measures. Another commenter credited the Hospital VBP Program with facilitating improvements in processes throughout hospitals. One commenter noted that it might support the proposal to remove process measures as a domain; however, it did not believe that process measures should be removed completely from the Hospital VBP Program. One commenter expressed concern that new process measures that may be developed in the future would be given the same weight as future outcome measures grouped in the same domain.

A few commenters noted that the four current Hospital VBP Program domains could accommodate process of care measures in the future, if needed.

Response: We did not intend to signal that we would no longer consider process measures in future program years. Rather, we agree with some commenters who noted that the four Hospital VBP Program domains, Safety, Clinical Care, Efficiency and Cost Reduction, and PCCEC/CC, are able to accommodate process of care measures in the future, if needed. Further, removing the distinction between process measures and outcome measures is in line with our stated policy of favoring outcome measures over process measures. We would consider adding more process measures if they will further the Hospital VBP Program's objectives.

Comment: One commenter did not support the proposed renaming of the Clinical Care—Outcomes subdomain.

Response: We believe renaming Clinical Care Outcomes subdomain to the Clinical Care domain gives us the flexibility to add process measures to that domain when appropriate in future program years.

Comment: One commenter requested that CMS clarify whether hospitals that elect to report six months of data for the PC–01 Elective Delivery measure as an eCQM for the Hospital IQR Program would also need to submit PC–01 Elective Delivery measure data using chart abstraction for the full year to have it included in the Hospital VBP Program scoring determination.

Response: Hospitals must submit PC–01 measure data based on chart abstraction for the Hospital IQR Program.

Comment: Several commenters supported the proposed recategorization of the PC–01 Elective Delivery measure as a Safety domain measure, as well as the proposed weight distribution in FY 2018.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing the proposal to move PC–01 to the Safety domain, remove the Clinical Care—Process subdomain, and rename the Clinical Care—Outcomes subdomain as the Clinical Care domain for the FY 2018 program year and subsequent years.

e. NHSN Measures Standard Population Data

The NHSN measures are calculated by CDC, and currently include the CAUTI, CLABSI, MRSA bacteremia, CDI, and Colon and Abdominal Hysterectomy SSI measures in the FY 2017 program year and subsequent program years. They measure the occurrence of these HAIs in hospitals participating in the Hospital VBP Program. In order to calculate the NHSN measures for use in both the Hospital IQR Program and the Hospital VBP Program, CDC must go through several steps. First, CDC determines each NHSN measure's number of predicted infections.[94] CDC determines the number of predicted infections using both specific patient care location characteristics (for example, number of days in which a patient in an ICU has a central line) and infection rates that occurred among a standard population (sometimes referred to by CDC as ''national baseline'' but referred to here as ''standard population data'').[95] Finally, for each NHSN measure, CDC calculates the Standardized Infection Ratio (SIR) by comparing a hospital's observed number of HAIs with the number of HAIs predicted for the hospital, adjusting for several risk factors.[96] For more information about the way NHSN measures are calculated, we refer readers to QualityNet's Web page on HAI measures, which may be found at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic* percent2FPage percent2F QnetTier2&cid=1228760487021.

As part of routine measure maintenance, CDC is updating the ''standard population data'' to ensure the NHSN measures' number of predicted infections reflect the current state of HAIs in the United States.[97] Currently, CDC calculates the ''standard population data'' for the CAUTI measure based on data it collected in CY 2009.[98] CDC calculates the ''standard population data'' for the CLABSI and Colon and Abdominal Hysterectomy SSI measures based on data it collected in 2006 to 2008.[99] CDC calculates the ''standard population data'' for the MRSA bacteremia and CDI measures based on data it collected in 2010 to 2011.[100] Beginning in 2015, CDC will collect data in order to update the standard population data for all of these NHSN measures (the CY 2015 standard population data for HAI measures will hereinafter be referred to as ''new standard population data'').

Because the Hospital VBP Program calculates improvement points using comparisons between data collected from hospitals in a baseline period and data collected in a performance period, the Hospital VBP Program must treat CDC's standard population data update differently than other quality programs. We have determined that we cannot equally compare CDC's ''new standard population data'' to the ''current standard population data'' in order to calculate improvement points. If we do not address the CDC's measure update, we will be unable to compare the baseline and performance periods for NHSN measures in the FY 2017 and FY 2018 program years. To address the problem, we intend to use the ''current standard population data'' to calculate performance standards and calculate

[94] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html.*

[95] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html.*

[96] Available at: *http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf.*

[97] Available at: *http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf.*

[98] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html#b6.*

[99] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html#b6.*

[100] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html#b6.*

and publicly report measure scores until the FY 2019 program year, as depicted in the table below. For the FY 2019 program year and subsequent years, the Hospital VBP Program will use the ''new standard population data'' to calculate performance standards and calculate and publicly report measure scores.

CDC'S STANDARD POPULATION DATA IN THE HOSPITAL VBP PROGRAM

	FY 2017 Program year*	FY 2018 Program year*	FY 2019 Program year**	FY 2020 Program year**
NHSN Measures Baseline Periods.	Current standard population data.	Current standard population data.	New standard population data.	New standard population data
NHSN Measures Performance Periods.	Current standard population data.	Current standard population data.	New standard population data.	New standard population data

* CDC will use ''current standard population data'' to calculate measure data that we will translate into scores on the measures.
** CDC will use ''new standard population data'' (CY 2015) to calculate measure data that we will translate into scores on the measures.

For a discussion addressing the ''new standard population data'' in the Hospital IQR Program, we refer readers to sections VIII.A.4.b. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24562) and this final rule.

Comment: Several commenters supported CMS' continuing use of the ''current standard population data'' to calculate performance standards until the FY 2019 program year because the strategy allows for accurate measurement between baseline and performance periods without readjusting the data to align with the ''new standard population data.'' One commenter noted this would help hospitals without an ICU capture more cases and better align with the HAC Reduction Program.

Response: We thank the commenters for their support.

Comment: One commenter supported the development of a plan to address CDC's NHSN new standard population data because they believe that the update will reflect significant progress toward elimination of HAIs especially for CLABSI. The commenter also believed that the update of the standard population data will assist in resetting the baseline for CAUTI, which they believe, has been challenging.

Response: We thank the commenter for its support.

Comment: One commenter supported the proposal to use new standard population data to calculate performance in both the baseline and performance periods, and urges CMS to consider the timing of this change to coincide with similar changes to these measures in the Hospital VBP Program.

Response: We thank the commenter for its support.

Comment: One commenter disagreed with the policy of using ''new standard population data'' beginning in the FY 2019 program year because the commenter believed that CMS should assess the impact of CDC's CY 2015 CAUTI ''standard population data'' based on substantive changes to surveillance criteria for the CAUTI measure.

Several commenters recommended that if assessment identifies potential problems, then CDC should use CY 2016 as the ''standard population data'' because it will be more stable. One commenter requested that CDC publish the differences from year-to-year collection.

Response: We appreciate the commenters' thoughts on stability of the 2015 data. CDC's new CAUTI definition was developed as a result of a subject matter expert working group comprised of CDC and non-CDC participants who systematically assessed each definitional component. The end result is a new CAUTI definition that is simplified from previous iterations and allows for less subjectivity while optimizing clinical credibility. An assessment of the impact of the definition change on CAUTI incidence was completed as part of the definition development. In addition, the NHSN application provides a technical infrastructure and built in controls on data entry that serve as safeguards against reporting of events that do not meet the new CAUTI definition. For these reasons, CDC is confident that the CAUTI data reported in 2015 will be appropriate to use for a new standard population.

f. Summary of Previously Adopted and Newly Adopted Measures for the FY 2018 Program Year

In summary, for the FY 2018 program, we are adopting the following measure set:

FY 2018 PREVIOUSLY ADOPTED AND NEWLY ADOPTED MEASURES

Patient and Caregiver-Centered Experience of Care/Care Coordination Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey
CTM–3*	3-Item Care Transitions Measure
Clinical Care Domain	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization
Safety Domain	
CAUTI	National Healthcare Safety Network Catheter-Associated Urinary Tract Infection Outcome Measure
CLABSI	National Healthcare Safety Network Central Line-Associated Bloodstream Infection Outcome Measure
Colon and Abdominal Hysterectomy SSI.	Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection Outcome Measure • Colon • Abdominal Hysterectomy

FY 2018 PREVIOUSLY ADOPTED AND NEWLY ADOPTED MEASURES—Continued

MRSA bacteremia	National Healthcare Safety Network Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* Bacteremia Outcome Measure
CDI	National Healthcare Safety Network Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection Outcome Measure
PSI–90	Patient Safety for Selected Indicators (Composite)
PC–01 **	Elective Delivery
Efficiency and Cost Reduction Domain	
MSPB–1	Payment-Standardized Medicare Spending Per Beneficiary

* Finalized new measure.
** Finalized to be moved from the Clinical Care—Process subdomain to the Safety domain.

3. Previously Adopted and Newly Adopted Measures for the FY 2019, FY 2021, and Subsequent Program Years

Due to the time necessary to adopt measures, we often adopt policies for the Hospital VBP Program well in advance of the program year for which they will be applicable (for example, 76 FR 26490 through 26547; 76 FR 51653 through 51660; 76 FR 74527 through 74547; 77 FR 53567 through 53614; 78 FR 50676 through 50707; 78 FR 75120 through 75121; 79 FR 50048 through 50087). In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24501 through 24503), we signaled our intent to include additional data in certain NHSN measures beginning with the FY 2019 program year, proposed to adopt a new measure beginning with the FY 2021 program year, and summarized all previously adopted and newly proposed measures.

a. Intent To Propose in Future Rulemaking To Include Selected Ward (Non-Intensive Care Unit (ICU)) Locations in Certain NHSN Measures Beginning With the FY 2019 Program Year

The Hospital VBP Program uses adult, pediatric, and neonatal intensive care unit (ICU) data to calculate performance standards and measure scores for the CAUTI and CLABSI measures for the FY 2017 and FY 2018 program years (79 FY 50061). In the FY 2014 IPPS/LTCH PPS proposed rule, we proposed under the Hospital IQR Program to expand the collection of CAUTI and CLABSI measures to include several selected ward (non-ICU) locations beginning with events occurring on or after January 1, 2014 (78 FR 27684). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50787), after consideration of the public comments received, we deferred the implementation date of the CAUTI and CLABSI measure expansion to selected ward (non-ICU) settings for the Hospital IQR Program from January 1, 2014 to January 1, 2015 (78 FR 50787). Selected ward (non-ICU) locations are defined as adult or pediatric medical, surgical, and medical/surgical wards (79 FY 50061; 78 FR 50787).

In the FY 2015 IPPS/LTCH PPS final rule, we signaled our intent to consider using data from selected ward (non-ICU) locations for the Hospital VBP Program, beginning in the FY 2019 program year for purposes of calculating performance standards for the CAUTI and CLABSI measures (79 FR 50061). In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24501 through 24502), we stated our intent to propose to include the selected ward (non-ICU) locations in the CAUTI and CLABSI measures beginning with the FY 2019 program year in future rulemaking. We intend to propose to adopt a baseline period of January 1, 2015 through December 31, 2015, and a performance period of January 1, 2017 through December 31, 2017, for the CAUTI and CLABSI measures. This expansion of the CAUTI and CLABSI measures would be consistent with the NQF re-endorsement update to these measures, which allows application of the measures beyond ICUs (78 FR 50787). We believe this expansion of the measures will allow hospitals that do not have ICU locations to use the tools and resources of the NHSN for quality improvement and public reporting efforts (78 FR 50787).

We invited public comment on this plan to accommodate these measures' expansions in the Hospital VBP Program future rulemaking.

Comment: Several commenters supported CMS' proposal to include performance data from non-ICU locations in the CLABSI and CAUTI measures starting in FY 2019, including the proposal to use FY 2019 as the first year for the newly revised measures. Several commenters noted that CLABSI and CAUTI measures are important targets for dedicated surveillance and prevention efforts outside the ICU setting. One commenter noted that the inclusion of the selected ward (non-ICU) locations in the Hospital VBP Program would represent a more robust reflection of organizational performance. Another commenter believes this proposal will allow hospitals that do not have ICU locations to use the tools and resources of the NHSN for their quality improvement efforts. Finally, one commenter noted that more hospitals will be able to submit data and be scored given the expansion. The commenter also commended CMS for waiting to integrate these measures into the Hospital VBP Program until there is a baseline and performance period using the same measure definition to allow for an achievement and improvement score.

Response: We thank the commenters for their support.

Comment: One commenter requested that CMS consider providing selected ward (non-ICU) locations with the mechanisms in the FY 2016 IPPS/LTCH PPS final rule to begin voluntarily collecting data related to the CAUTI and CLABSI measures for purposes of calculating performance standards.

Response: We note that data collection began under the Hospital IQR Program on January 1, 2015 and the first submission deadline to NHSN does not occur until after publication of the FY 2016 IPPS/LTCH PPS final rule. We intend to include performance standards in the FY 2017 IPPS/LTCH PPS proposed and final rules.

Comment: Several commenters urged CMS to carefully review the data submitted to determine its appropriateness for inclusion in the program.

Response: We thank the commenters for their suggestion, and we will take the comments and suggestions into consideration in future rulemaking. We review all the Hospital VBP Program data provided from NHSN, and, in concert with CDC, will conduct appropriate analyses on the data provided.

Comment: One commenter supported CMS' proposal to include performance data from non-ICU locations in the CLABSI and CAUTI measures, but the commenter objected to the proposal to postpone the adoption of these NQF-

endorsed measures until 2019 feeling that this is too delayed given the extent of morbidity and mortality associated with these infections.

Response: We thank the commenter for the suggestion, but note that we cannot adopt the measures earlier than the FY 2019 program year because of statutory and other restrictions on measures entering the program.

Comment: One commenter did not support the expansion of CAUTI data collection to non-ICU wards because a subset of patients, for example, spinal cord injury/dysfunction patients, may be in danger of receiving improper care unless they are excluded from the measure. These patients are often hospitalized after trauma and may experience over distension of the bladder and dysenergic uropathy if their bladder management is not performed appropriately. The commenter noted that some hospitals remove the catheter prematurely as a result of the CAUTI measure, often without recognizing spinal cord injury patients as an at-risk population, which can result in improper and unsafe bladder management.

Response: We agree that patients with spinal cord injury/dysfunction require careful evaluation for bladder dysfunction and proper emptying practices. However, we do not believe that this is a reason to exclude patients from CAUTI surveillance. Patients with spinal cord injury/dysfunction are at risk of CAUTI, and frequent use of indwelling urinary catheters on a long-term basis places a premium on proper insertion and maintenance practices.

Comment: Some commenters supported CMS' inclusion of the expanded scope of surveillance and recommended that CMS add detail on how the SIR metric for CAUTI and CLABSI will be calculated and used for public reporting, given that there has been little experience or use of a blend of types of locations into an overall SIR. One commenter recommended that CMS work with CDC's NHSN subject matter experts to better understand the impact of the expanded scope prior to adoption. One commenter also suggested that CMS improve the risk adjustment for the CLABSI, CAUTI, and CDI.

Response: The SIR is a risk-adjusted summary measure that takes into account the variability of HAI incidence among different patient populations (for example, ICU vs. non-ICU patients). CDC will perform in-depth analyses of the 2015 data to determine an appropriate baseline for the inclusion of non-ICU data in future CLABSI and CAUTI SIRs.

We thank the commenters for their views on our intent to propose to include the selected ward (non-ICU) locations in the CAUTI and CLABSI measures beginning with the FY 2019 program year in future rulemaking.

b. New Measure for the FY 2021 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893)

Hospital 30-Day, All-Cause, RSMR following COPD Hospitalization (NQF #1893) (MORT–30–COPD) is a risk-adjusted, NQF-endorsed mortality measure monitoring mortality rates following COPD hospitalizations. We adopted this measure in the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50792). Initial measure data were posted on *Hospital Compare* in December 2014 and the full measure specifications are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Chronic lower respiratory disease (including COPD) is the third leading cause of death in the United States.[101] Between 1998 and 2008, the number of patients hospitalized annually for acute exacerbations of COPD increased by approximately 18 percent.[102] [103] [104] Moreover, COPD is one of the top 20 conditions contributing to Medicare costs.[105] The median 30-day RSMR following admissions for COPD between July 2010 and June 2013 was 7.8 percent with variation in mortality rates ranging from 5.5 percent to 12.4 percent across over 2,700 hospitals.[106]

The MAP supported the inclusion of the MORT–30–COPD measure in the Hospital VBP Program as detailed in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [107] The MAP noted that the addition of the MORT–30–COPD measure would be appropriate as 30-day mortality rate measures for AMI, HF, and PN are already part of the Hospital VBP Program measure set.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24502), we proposed this measure for the Hospital VBP Program based on the MAP recommendation, our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least 1 year prior to the start of the performance period. In addition, the MORT–30–COPD measure is appropriate for the Hospital VBP Program because it addresses a high volume, high cost condition, and chronic lower respiratory disease (including COPD) is the third leading cause of mortality in the United States. The measure aligns with the CMS Quality Strategy Goal of Effective Prevention and Treatment. Based on the continued high risk of mortality after COPD hospitalizations, we proposed to add it to the Clinical Care domain for the FY 2021 program year.

We invited public comment on this proposal.

Comment: Several commenters supported the adoption of the MORT–30–COPD measure for the FY 2021 program year because this measure will advance the treatment, management, and care coordination required for COPD hospitalizations, resulting in better outcomes for patients and a reduction in overall costs. One commenter believed this measure will increase incentives for hospitals to better manage COPD for patients after discharge.

Response: We thank the commenters for their support.

Comment: Several commenters requested that CMS consider an earlier adoption of the MORT–30–COPD measure for the FY 2019 program year, with data collection beginning in FY 2017 to align with the Hospital Readmissions Reduction Program requirements.

Response: We are unable to implement the measure in the Hospital

[101] Hoyert DL, Xu JQ. Deaths: preliminary data for 2011. *Natl Vital Stat Rep.* 2012;61(6):1–65. Hyattsville, MD: National Center for Health Statistics.2012. Available at: *http://www.birthbythenumbers.org/wp-content/uploads/2012/12/prelim-deaths-2011.pdf*.

[102] National Heart L, and Blood Institute, The Morbidity & Mortality: Chart Book on Cardiovascular, Lung and Blood Diseases. 2009; Available at: *http://www.nhlbi.nih.gov/resources/docs/2009_ChartBook.pdf*.

[103] The Centers for Disease Control and Prevention. National Center for Health Statistics Chronic Lower Respiratory Disease. FastStats 2010; Available at: *http://www.cdc.gov/nchs/fastats/copd.htm*.

[104] Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project Statistics on Hospitals Stays. 2009; Available at: *http://hcupnet.ahrq.gov/*.

[105] Andrews RM. The National Hospital Bill: The Most Expensive Conditions by Payer, 2006. Rockville: Agency for Healthcare Research and Quality; 2008.

[106] September 2014 Medicare Hospital Quality Chartbook Performance Report on Outcome Measures. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*.

[107] National Quality Forum ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/* and ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' found at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx*.

VBP Program sooner than the FY 2021 program year because, as we discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24505), we proposed to adopt the measure for a future program year in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. As we stated in the proposed rule (80 FR 24504), we believe a 36-month baseline and performance period is appropriate for the mortality measures when possible. Adopting the MORT–30–COPD measure for the FY 2021 program year also aligns the measurement periods for all the 30-day mortality measures in the program.

Comment: Many commenters did not support CMS' proposal to adopt the MORT–30–COPD measure. The commenters urged CMS to adjust for sociodemographic status because COPD is a condition sensitive to environmental factors and exacerbations of the condition can be related to the patient's sociodemographic status.

Commenters expressed concern with the measure's reliability. The commenters noted that testing results showed only moderate reliability. These commenters recommended that CMS develop a plan to improve or replace the claims-based mortality measures used in the Hospital VBP Program.

One commenter suggested that MORT–30–COPD is not a good measure of a hospital's evidence-based quality practices for COPD. Another commenter suggested that hospitals will be penalized twice in two different programs. Finally, one commenter noted that the current form of the measure does not address end of life or palliative care, which greatly affects hospitals that specialize in these areas of service.

Response: As we have explained above, while we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures. To date, we have found that hospitals that care for large proportions of patients of low sociodemographic status are capable of performing well on our measures (we refer readers to the 2014 Chartbook pages 48–57, 70–73, and 78 at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*).

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we acknowledge the commenters' concerns regarding the measure's reliability, we note that we use the same statistical approach to reliability for the COPD mortality measure that we have established for our other hospital risk-adjusted outcome measures. Reliability is related to sample-size, and we adopted a risk-adjustment modeling methodology that takes into account sample size. Moreover, as stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53591) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50693), we believe that the mortality measures capture important quality data for purposes of the Hospital VBP Program. We believe that the claims-based mortality measures are sufficiently reliable for inclusion in the Hospital VBP Program, and they are NQF-endorsed.

We disagree with the commenter that the COPD mortality measure is not a good measure of evidenced-based quality practices, as high quality care is necessary to achieve low mortality rates. In regard to the commenter's concern that the measure does not address end-of life or palliative care, we note that patients enrolled in hospice any time in the 12 months prior to the index admission, including the first day of the index admission, are excluded from the measure because mortality is not necessarily an adverse outcome or indicator of poor quality care in this population. However, the measure does not exclude patients who transition to hospice or palliative care because such transitions may be the result of quality failures that have led to poor clinical outcomes.

Comment: One commenter noted that the mortality rate is high for patients with COPD, and the commenter encouraged CMS to monitor hospitals to ensure that they do not discourage admission of COPD patients in order to score better on the measure.

Response: We acknowledge the commenter's concern and recognize that any performance-based payment program may create the potential for unintended consequences. However, we remain committed to monitoring and assessing unintended consequences, such as changes in utilization, and adjusting the program as needed. In order to assess trends in measure performance and healthcare utilization, we continuously analyze our measures, including the MORT–30–COPD measure, and publish our findings annually in the ''Medicare Hospital Quality Chartbook'' at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/OutcomeMeasures.html*.

Comment: One commenter urged CMS to use the years between now and FY 2021 to ensure the validity of the proposed measure and ensure that information attained from using this measure will improve the quality of care for patients prior to moving forward with implementation plans for FY 2021.

Response: We appreciate the commenter's suggestion, but note that the measure has been tested and validated for the acute inpatient setting. We also note that NQF has endorsed the measure as valid and reliable (NQF #1893).

After consideration of the public comments we received, we are finalizing the proposal to add MORT–30–COPD to the FY 2021 program year and subsequent years.

c. Summary of Previously Adopted and Newly Adopted Measures for the FY 2019 and FY 2021 and Subsequent Program Years

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50063), we finalized our proposal to adopt the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary THA/TKA measures for the FY 2019 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50063

through 50065), we also finalized our proposal to adopt the PSI–90 measure for the FY 2019 program year and subsequent years.

FY 2019 PREVIOUSLY ADOPTED MEASURES

Clinical Care Domain	
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty/Total Knee Arthroplasty.
Safety Domain	
PSI–90	Patient Safety For Selected Indicators (Composite).

In this final rule, we are finalizing our proposal to adopt the MORT–30–COPD measure for the FY 2021 program year and subsequent years.

FY 2021 NEWLY ADOPTED MEASURE

Clinical Care Domain	
MORT–30–COPD.	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization.

4. Possible Measure Topics for Future Program Years

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50066 through 50070), we responded to comments on measures that could potentially be used to expand the Efficiency and Cost Reduction domain in the future. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24503), we again sought public comments on this issue. We indicated that we were interested in expanding the Efficiency and Cost Reduction domain to include a more robust measure set, which may include measures that supplement the MSPB measure with more condition and/or treatment specific episode measures. In the FY 2016 IPPS/LTCH PPS proposed rule, we also encouraged comment on Efficiency and Cost Reduction measures already included in the Hospital IQR Program as well as measures we proposed in section VIII.A.7. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24566 through 24581) for inclusion in the Hospital IQR Program beginning with the FY 2018 payment determination.

Comment: We received a number of comments related specifically to the proposed clinical episode-based payment measures themselves.

Response: We thank the commenters for their input regarding the four clinical episode-based measures we proposed for the Hospital IQR Program. We have addressed these comments in section VIII.A.7.b. of the preamble of this final rule. We note that we are finalizing three of the four proposed measures: (1) Kidney/UTI Clinical Episode-Based Payment Measure (claims-based); (2) Cellulitis Clinical Episode-Based Payment Measure (claims-based); and (3) Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (claims-based) for the Hospital IQR Program, but not beginning with the FY 2018 payment determination as proposed. Instead, we are finalizing these measures beginning with the FY 2019 payment determination and will provide data to hospitals on these measures in confidential hospital-specific reports before the measures are included in the Hospital IQR Program. We refer readers to section VIII.A.7.b. of the preamble of this final rule for further details. In order to include these measures in the Hospital VBP Program in the future, we would have to propose and finalize related policies through future notice and comment rulemaking.

We also received several comments related to the potential future inclusion of the clinical episode-based payment measures in the Hospital VBP Program. We summarize and respond to those comments below.

Comment: Several commenters supported a more granular episode-based payment measure in place of, rather than in addition to, the MSPB–1 measure.

Response: We thank the commenters for their support of the episode-based payment measures. We continue to believe that the MSPB measure provides valuable information about Medicare spending. We would propose any changes to the efficiency domain measure set through future rulemaking.

Comment: One commenter recommended that instead of adding duplicative, condition-specific Efficiency and Cost Reduction measures, CMS should improve the ''predictive power'' of the existing MSPB–1 measure through stronger risk-adjustment.

Response: We do not believe that the clinical episode-based pending measures are duplicative of the existing MSPB–1 measure. Rather, the measures provide a more complete picture of Medicare spending, in order to allow hospitals to better understand and target their efficiency efforts. The MSPB–1 measure has been endorsed by the NQF. It is considered to be a valid, reliable measure of Medicare spending.

Comment: One commenter did not support CMS' possible addition of episode-based efficiency measures if it is possible that certain hospitals may be penalized twice if the hospitals have both high procedure costs and a high MSPB–1 rate unless we can ensure that hospitals with a high volume of patients—especially those with complex patients for an episode condition or surgery—are not inappropriately penalized, rewarded, or otherwise scrutinized as a result of performance on overlapping measures. The commenter asked that CMS specify the combination of diagnosis codes and procedures needed to define clinically relevant services for this episode-based efficiency measure.

Response: As we note in section VIII.A.7.b. of the preamble of this final rule, we developed these measures in response to public comment requesting that we develop a more robust efficiency measure set and that we include measures that are inclusive of clinically-

related services. While performance on the overall Medicare spending measure may correlate with performance on the clinical episode-based measures, we believe that they will provide valuable additional information.

Comment: A few commenters urged CMS to continue exploring additional measures of cost and efficiency for the program, arguing that the value of care provided is a function of both quality and cost, where both elements carry equal weight. One commenter urged us to establish a policy goal and specific plan to incrementally increase the efficiency domain to 50 percent of the TPS as more efficiency measures are developed and added to the program.

Response: We thank commenters for their input and we will take it into consideration in future rulemaking.

Comment: Commenters suggested reducing the weight of the Efficiency domain during future initial implementation of new episode-based measures until we have adequate experience using the new measures.

Response: We thank the commenters for their input regarding the four clinical episode-based measures we proposed for the Hospital IQR Program. We note that we are finalizing three of the four proposed measures: (1) Kidney/UTI Clinical Episode-Based Payment Measure (claims-based); (2) Cellulitis Clinical Episode-Based Payment Measure (claims-based); and (3) Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (claims-based) for the Hospital IQR Program, but not beginning with the FY 2018 payment determination as proposed. Instead, we are finalizing them beginning with the FY 2019 payment determination and will provide data to hospitals on these measures in confidential hospital-specific reports before the measures are included in the Hospital IQR Program. We refer readers to section VIII.A.7.b. of the preamble of this final rule for further details.

Comment: One commenter recommended that CMS explore utilization measures that reflect the appropriateness of service use and intensity in hospitals for inclusion in the Efficiency and Cost Reduction domain.

Response: We thank commenter for this input regarding Efficiency and Cost Reduction domain.

Comment: One commenter supported efficiency measures that are linked closely to hospital services.

Response: We thank commenter for this input regarding the Efficiency and Cost Reduction domain.

Comment: One commenter requested that CMS disaggregate by clinical service line and that CMS provide the number of episodes per service line for certain files on *Hospital Compare,* including data that shows the breakdown of spending per episode on physician, inpatient, outpatient, durable medical equipment, home care, and nursing home services during admission and post-discharge. The commenter noted that this information is already provided to individual hospitals, but it would be more useful if hospitals and their agents could compare results among hospitals.

Response: A ''Medicare Hospital Spending by Claim'' table is currently available on *Hospital Compare* at: *http://www.medicare.gov/hospitalcompare/Data/spending-per-hospital-patient.html.* The table divides each hospital's average episode spending levels into three time periods: (1) During the 3 days prior to the index admission; (2) during the index admission; and (3) during the 30 days after hospital discharge. Within the time periods, the average episode spending levels are further broken down into seven service types (for example, inpatient or outpatient).

We also received several comments providing thoughts on other new measures for us to add in future program years:

Comment: Several commenters encouraged CMS to develop a measure that captures information about patient transitions to outpatient care, arguing that as hospitals are taking on a greater role in post-acute care coordination, understanding how well efforts to connect patients with external providers and social support systems will contribute to a critical gap.

Response: We thank the commenters for their suggestions, and we will take them into consideration in future rulemaking.

Comment: One commenter encouraged CMS to develop a measure that incorporates healthcare workers in home and community-based services.

Response: We thank the commenter for this suggestion, and we will take it into consideration in future rulemaking.

Comment: One commenter recommended that CMS explore implementing measures of advance care planning because proper end-of-life planning discussions reduce related costs of care. The commenter suggested an advanced care plan in an electronic medical record as a measure.

Response: We thank the commenter for these suggestions, and we will take them into consideration in future rulemaking.

Comment: One commenter suggested that CMS consider CABG and/or Stroke mortality measures.

Response: We thank the commenter for these suggestions, and we will take them into consideration in future rulemaking.

Comment: One commenter recommended that CMS consider including the cost of anesthesia delivery models as a future measure in the Efficiency and Cost Reduction domain because peer-reviewed literature indicates that Certified Registered Nurse Anesthetists (CRNAs) acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery without any measurable difference in quality of care. This commenter also suggested that CMS consider the costs incurred by (1) an anesthesiologist being ''present at induction'' and (2) an anesthesiologist being ''present at emergence'' from anesthesia. The commenter noted that waiting costs due to delayed starts to surgery lead to postponing the surgery schedule, overtime for staff, delaying surgeon's rounds that affect patient care and discharge of the patient, opportunity costs, and diversion of resources from other patient care. The commenter noted that the literature shows that anesthesiologists fail to comply with federal requirements and noted lapses in anesthesiologist supervision is common which adds hospital costs while the patient remains anesthetized.

Response: We thank the commenter for these suggestions, and we will take them into consideration in future rulemaking.

Comment: One commenter suggested adding the cost of anesthesia subsidies per anesthetizing location as part of the Efficiency and Cost Reduction domain because a new measure on spending on subsidies information could support hospitals in determining and adopting the most efficient model of anesthesia care based on their needs.

Response: We thank the commenter for this suggestion and we will take it into consideration in future rulemaking.

Comment: One commenter suggested that CMS adopt the STK–04 measure because strokes leave many with new disabilities and increased health risks, and the commenter believed we should prioritize outcome measures related to stroke.

Response: We thank the commenter for this suggestion, and we will take it into consideration in future rulemaking.

Comment: One commenter suggested that CMS prioritize adding NQF #0500, the Severe Sepsis and Septic Shock Management Bundle, to the Hospital VBP Program and noted that it has been

added to the Hospital IQR Program for FY 2017.

Response: We thank the commenter for this suggestion, and we will take it into consideration in future rulemaking.

Comment: A few commenters recommended that CMS prioritize implementation of a nutrition or malnutrition-related quality measure set as soon as feasible because malnutrition is a patient safety risk and an independent predictor of negative patient outcomes including mortality, length of hospital stay, readmissions, and hospitalization cost. The commenters noted that malnutrition gap areas include lack of systematic: (1) Screening, assessment, and nutrition intervention; (2) execution of nutrition care plans upon admission through discharge; and (3) care coordination to home or other post-acute care sites.

Response: We thank the commenters for their suggestions, and we will take these comments into consideration in future rulemaking.

Comment: A few commenters suggested that CMS adopt the PSI–4: Death among surgical inpatients with serious treatable complications measure and the AMI Payment per Episode measure.

Response: We thank the commenters for their suggestions, and we will take these comments into consideration in future rulemaking.

Comment: One commenter suggested that CMS fill measurement gaps so that a broader perspective of the quality of care rendered can be assessed. Specifically, the commenter suggested that CMS include outcome measures related to medication errors, mental and behavioral health, arthritis, diabetes, chronic kidney disease, depression, Alzheimer's disease, ischemic heart disease, stroke/transient ischemic attack, breast cancer, colorectal cancer, hip/pelvic fracture, cataract, osteoporosis, glaucoma, and endometrial cancer. The commenter noted that many outcome measures for those conditions may not yet exist, but the commenter suggested that the recently enacted Medicare Access and CHIP Reauthorization Act provided for measurement development funding, which could be directed toward developing measures to fill in these gaps.

Response: We thank the commenter for these suggestions, and we will take these comments into consideration in future rulemaking. We note that the funding for measurement development provided in section 1848(s) of the Act, as added by section 102 of the Medicare Access and CHIP Reauthorization Act of 2015, can only be used to develop measures for use by physicians and other eligible professionals. The statute states that the funding must be used to carry out section 1848(s) of the Act, including, but not limited to, the development, improvement, updating, or expansion of measures in accordance with the final measure development plan that the Secretary is required to post by May 1, 2016. The measures that are developed with this funding must be specifically targeted for application under the quality performance category of the Merit-Based Incentive Payment System under section 1848(q)(2)(B)(i) of the Act or under the qualifying alternative payment model participant provisions under section 1833(z)(2)(C) of the Act.

Comment: One commenter recommended that CMS adopt the patient falls with injury or patient falls rate for future program years.

Response: We thank the commenter for this suggestion, and we will take these comments into consideration in future rulemaking.

Comment: One commenter contended that chart-abstracted process of care measures should not be replaced by parallel eCQM ones in the Hospital VBP Program until all hospitals are reporting the same measures electronically and an appropriate data validation process is in place.

Response: We thank the commenter for this suggestion, and we will take these comments into consideration in future rulemaking.

Comment: One commenter encouraged the continued harmonization of COPD measures across all programs and supported the development of measures addressing care gaps, specifically management of poorly controlled COPD, so that patients utilize the right therapies and predict risk for exacerbation.

Response: We thank the commenter for these suggestions, and we will take these comments into consideration in future rulemaking.

Comment: One commenter noted that the excess acute care days after hospitalization are explicitly prohibited from inclusion in the Hospital VBP Program because the composite measures for AMI and HF contain a measure of readmissions.

Response: We thank the commenter for this interpretation, and we will take it into consideration in future rulemaking.

Comment: Several commenters did not support adding excess day measures until there is additional analysis. The commenters believed these measures need to be NQF reviewed to ensure they are valid, reliable and feasible as well as appropriate for review in the NQF sociodemographic trial period. The commenters also recommended, rather than adding new measures, CMS should review our multiple bundling initiatives and ensure these measures are aligned.

Response: We thank the commenters for their thoughts, and we will take these comments into consideration in future rulemaking.

5. Previously Adopted and Newly Adopted Baseline and Performance Periods for the FY 2018 Program Year

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 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087) for the baseline and performance periods for the Clinical Care—Process, PCCEC/CC, Clinical Care—Outcomes, and Efficiency and Cost Reduction domains that we have adopted for the FY 2017 program year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50692 through 50694), we adopted baseline and performance periods for the 30-day mortality measures for FY 2017, FY 2018, and FY 2019, and for the PSI–90 measure for FY 2017 and FY 2018 (78 FR 50692 through 50694, 50698 through 50699).

b. Baseline and Performance Periods for the Patient and Caregiver-Centered Experience of Care/Care Coordination Domain for the FY 2018 Program Year

Since the FY 2015 program year, we have adopted a 12-month baseline period and 12-month performance period for measures in the PCCEC/CC domain (77 FR 53598; 78 FR 50692; 79 FR 50072). We continue to believe that a 12-month performance period for the HCAHPS Survey and proposed CTM–3 measure provides us sufficient data on which to score hospital performance, which is an important goal for both us and stakeholders. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24503), for the FY 2018 program year, we proposed to adopt a 12-month performance period of January 1, 2016 through December 31, 2016 for the PCCEC/CC domain. We also proposed to adopt a corresponding 12-month baseline period of January 1, 2014 through December 31, 2014 for purposes of calculating improvement points and calculating performance standards.

We invited public comment on these proposals.

We did not receive any public comments on these proposals, and we

are finalizing the baseline and performance period as proposed.

c. Baseline and Performance Periods for NHSN Measures and PC–01 in the Safety Domain for the FY 2018 Program Year

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for NHSN measures (78 FR 75121; 79 FR 50071). In addition, we adopted the PC–01 measure for the FY 2017 program year with a 12-month baseline period and 12-month performance period (79 FR 50072). We continue to believe that a 12-month performance period provides us with sufficient data on which to score hospital performance on the NHSN measures, as well as the PC–01 measure, in the Safety domain. We also note that 12-month baseline and performance periods are consistent with the reporting periods used for these measures under the Hospital IQR Program. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24503), for the FY 2018 program year, we proposed to adopt a performance period of January 1, 2016 through December 31, 2016 for the NHSN measures and the PC–01 measure in the Safety domain. We also proposed to adopt a corresponding baseline period of January 1, 2014 through December 31, 2014 for purposes of calculating improvement points and calculating performance standards.

We invited public comment on these proposals.

Comment: One commenter supported the proposal to use 12-month baseline and performance periods for the CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA bacteremia measures.

Response: We thank the commenter for its support.

After consideration of the public comment we received, we are finalizing the baseline and performance periods as proposed.

d. Baseline and Performance Periods for the Efficiency and Cost Reduction Domain for the FY 2018 Program Year

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for the MSPB–1 measure in the Efficiency and Cost Reduction domain (79 FR 50072; 78 FR 50692). These baseline and performance periods enable us to collect sufficient measure data, while allowing time to calculate and incorporate MSPB–1 measure data into the Hospital VBP Program scores in a timely manner. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24503), for the FY 2018 program year, we proposed to adopt a 12-month performance period of January 1, 2016 through December 31, 2016 for the MSPB–1 measure in the Efficiency and Cost Reduction domain. We also proposed to adopt a corresponding baseline period of January 1, 2014 through December 31, 2014. We note that these proposed baseline and performance periods align with the baseline and performance periods for the PCCEC/CC domain and all measures in the Safety domain with the exception of PSI–90.

We invited public comment on these proposals.

We did not receive any public comments on these proposals, and we are finalizing the baseline and performance period as proposed.

e. Summary of Previously Adopted and Newly Adopted Baseline and Performance Periods for the FY 2018 Program Year

The table below summarizes the baseline and performance periods for the FY 2018 program year (with previously adopted baseline and performance periods for the mortality and PSI composite (PSI–90) measures noted). We note that we are finalizing our proposal, discussed above, to remove the Clinical Care—Process subdomain from the Hospital VBP Program beginning with the FY 2018 program year. We note further that these baseline and performance periods would continue to align with the PCCEC/CC domain and the Efficiency and Cost Reduction domain, as well as the periods proposed for certain measures in the Safety domain.

PREVIOUSLY ADOPTED AND NEWLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2018 PROGRAM YEAR

Domain	Baseline period	Performance period
PCCEC/CC:		
• HCAHPS Survey	January 1, 2014–December 31, 2014	January 1, 2016–December 31, 2016.
• CTM–3		
Clinical Care:		
Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN)*.	October 1, 2009–June 30, 2012	October 1, 2013–June 30, 2016.
Safety:		
• PSI–90*	• July 1, 2010–June 30, 2012	• July 1, 2014–June 30, 2016.
• PC–01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2014–December 31, 2014	• January 1, 2016–December 31, 2016.
Efficiency and Cost Reduction MSPB–1	January 1, 2014–December 31, 2014	January 1, 2016–December 31, 2016.

* Previously adopted baseline and performance periods.

6. Previously Adopted and Newly Adopted Baseline and Performance Periods for Future Program Years

a. Previously Adopted Baseline and Performance Periods for the FY 2019 Program Year

The table below summarizes the previously adopted baseline and performance periods for the Clinical Care domain and PSI–90 measures for the FY 2019 program year.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2019 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN).	• July 1, 2009–June 30, 2012	• July 1, 2014–June 30, 2017.
• THA/TKA	• July 1, 2010–June 30, 2013	• January 1, 2015–June 30, 2017.*
Safety:		
• PSI–90	• July 1, 2011–June 30, 2013	• July 1, 2015–June 30, 2017.

*The table in FY 2016 IPS/LTCH PPS proposed rule (80 FR 24505) inadvertently stated that this performance period is July 1, 2015–June 30, 2017. However, as adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50073), this performance period is January 1, 2015–June 30, 2017.

b. Baseline and Performance Periods for the PSI–90 Measure in the Safety Domain in the FY 2020 Program Year

The table below summarizes the previously adopted and proposed baseline and performance periods for the FY 2020 program year that we proposed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24504). In the FY 2020 program year, we proposed to adopt a performance period of July 1, 2016 to June 30, 2018 for the PSI–90 measure. We proposed a corresponding baseline period of July 1, 2012 to June 30, 2014. This will allow us to collect 24-months of data from hospitals on the PSI–90 measure.

PREVIOUSLY ADOPTED AND NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2020 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN)*.	July 1, 2010–June 30, 2013	July 1, 2015–June 30, 2018.
• THA/TKA*.		
Safety:		
PSI (PSI–90) Measure	July 1, 2012–June 30, 2014	July 1, 2016–June 30, 2018.

*Previously adopted baseline and performance periods

We invited comment on these proposals.

We did not receive any public comments on these proposals, and we are finalizing the baseline and performance period as proposed.

c. Baseline and Performance Periods for the Clinical Care Domain for the FY 2021 Program Year

The table below summarizes the proposed baseline and performance periods for the FY 2021 program year that we proposed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24504 through 24505). In the FY 2014 IPPS/LTCH PPS and FY 2015 IPPS/LTCH PPS final rules (78 FR 50692 through 50694; 79 FR 50072 through 50073), we adopted baseline and performance periods for the three 30-day mortality measures for the FY 2017, FY 2018, FY 2019, and FY 2020 program years. We adopted baseline and performance periods for the THA/TKA measure for the FY 2019 and FY 2020 program years (79 FR 50073). We adopted this policy in light of the length of the performance period that is needed to collect enough measure data for reliable performance scoring. We continue to believe that we should adopt 36-month baseline and performance periods for the mortality measures when possible to accommodate those durations.

We believe that a similar rationale applies to the new MORT–30–COPD measure that we proposed to adopt for the Clinical Care domain for the FY 2021 program year. Furthermore, we are attempting to align measurement periods under the Hospital VBP Program with measurement periods under the Hospital IQR Program for the 30-day mortality measures. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24504 through 24505), for the FY 2021 program year, we proposed to adopt a 36-month performance period of July 1, 2016 through June 30, 2019 for all mortality measures (the three previously adopted mortality measures, as well as the proposed MORT–30–COPD measure) in the Clinical Care domain. We also proposed to adopt a corresponding baseline period of July 1, 2011 through June 30, 2014. We note that the proposed performance periods will align with the reporting periods for the mortality measures in the Hospital IQR Program for the first time.

For the THA/TKA measure in the FY 2021 program year, we proposed to adopt a 36-month performance period of April 1, 2016 through March 31, 2019. We also proposed to adopt a corresponding baseline period of April 1, 2011 through March 31, 2014. This baseline and performance period will align with the THA/TKA measure reporting period for the Hospital IQR Program and will make reporting more seamless for hospitals.

We invited public comment on these proposals.

PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2021 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD).	• July 1, 2011–June 30, 2014	• July 1, 2016–June 30, 2019.
THA/TKA	• April 1, 2011–March 31, 2014	• April 1, 2016–March 31, 2019.

We did not receive any public comments on these proposals, and we are finalizing the baseline and performance period as proposed.

7. 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 not 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.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53599 through 53604), we adopted performance standards for the FY 2015 program year and certain FY 2016 program year measures. We also finalized our policy to update performance standards for future program years via notice on the CMS Web site or another publicly available Web site. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50694 through 50698), we revised our regulatory definitions of ''achievement threshold'' and ''benchmark'' at 42 CFR 412.160 and adopted performance standards for additional FY 2016 program year measures. We also adopted an interpretation of ''achievement threshold'' and ''benchmark'' under 42 CFR 412.160 to exclude the numerical values that result when the performance standards are calculated. We have further adopted a policy under which we may update a measure's performance standards for a fiscal year once if we identify data issues, calculation errors, or other problems that would significantly affect the displayed performance standards (79 FR 50079). We refer readers to the FY 2014 IPPS/LTCH PPS final rule for the complete set of FY 2016 performance standards (78 FR 50697 through 50698).

b. Technical Updates

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50077 through 50079), we adopted a policy under which we may adopt technical updates to performance standards under the Hospital VBP Program. We adopted this policy by amending the definition of ''performance standards'' under 42 CFR 412.160 of our regulations to enable us to update performance standards' numerical values to incorporate nonsubstantive technical updates made to Hospital VBP Program measures between the time that they are adopted for a particular program year and the time that we actually calculate hospital performance on those measures after the performance period for the program year has concluded. We stated our intent to continue to use rulemaking to adopt substantive updates to measures adopted for the Hospital VBP Program. We stated that examples of changes that we might consider to be substantive include 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. However, we stated our intent to determine what constitutes substantive versus nonsubstantive changes on a case-by-case basis, although we affirmed our intent to be as transparent as possible with stakeholders about any such updates we might adopt.

On January 29, 2015, we announced a technical update to the performance standards that we have adopted for the PSI–90 measure for the FY 2017 program year. The announcement was published on QualityNet and can be viewed at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublicpercent2FPage percent2FQnetBasic&cid=1228774624610.* The update resulted from a more recent AHRQ Quality Indicator software version becoming available. The FY 2017 performance standards were initially calculated using Version 4.4 of the AHRQ software, and the update allowed us to use Version 4.5a for both the performance standards and hospital results.

For more detailed information on the updates implemented in Version 4.5a, we refer readers to the Log of Coding Updates and revisions, posted on QualityNet, available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublicpercent2FPage percent2FQnetTier4&cid=1228695355425.* For more information on differences between Version 4.5a and previous versions of the software, we refer readers to the AHRQ Web site, available at: *http://qualityindicators.ahrq.gov* or to the AHRQ help desk directly, available at: *QIsupport@ahrq.hhs.gov* or (307) 427–1949.

c. Performance Standards for the FY 2018 Program Year

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24506 through 24507), 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 proposed to adopt the following additional performance standards for the FY 2018 program year. We noted that the numerical values for the performance standards displayed below represent estimates based on the most recently available data, and we stated that we intended to update the numerical values in the FY 2016 IPPS/LTCH PPS final rule. We note further that the MSPB–1 measure's performance standards are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time.

We note further that the performance standards for the NHSN measures, the PSI–90 measure, and the MSPB–1 measure are calculated with lower values representing better performance. This distinction is made in contrast to other measures for which higher values indicate better performance. As discussed further in the FY 2014 IPPS/LTCH PPS final rule, the performance standards for the Colon and Abdominal Hysterectomy SSI are computed separately for each procedure stratum, and we will first award achievement and improvement points to each stratum separately, then compute a weighted average of the points awarded to each stratum by predicted infections (78 FR 50684).

We note that the achievement threshold and benchmarks for the PSI–90, MORT–30–AMI, MORT–30–HF, and MORT–30–PN measures have not been updated from the FY 2016 IPPS/LTCH PPS proposed rule because those performance standards were based on the most recent data available. All other measures have been updated to reflect new data in the chart below.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2018 PROGRAM YEAR: SAFETY, CLINICAL CARE, AND EFFICIENCY AND COST REDUCTION MEASURES

Measure ID	Description	Achievement threshold	Benchmark
Safety Measures			
CAUTI *	National Healthcare Safety Network Catheter-associated Urinary Tract Infection Outcome Measure.	0.906	0.000
CLABSI *	National Healthcare Safety Network Central Line-associated Bloodstream Infection Outcome Measure.	0.369	0.000
CDI *	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection Outcome Measure.	0.794	0.002
MRSA bacteremia *	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure.	0.767	0.000
PSI–90 ± *	Patient safety for selected indicators (composite).	0.577321	0.397051
Colon and Abdominal Hysterectomy SSI *.	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection Outcome Measure.		
	• Colon	• 0.824	• 0.000
	• Abdominal Hysterectomy	• 0.710	• 0.000
PC–01	Elective Delivery	0.020408	0.000
Clinical Care Measures			
MORT–30–AMI ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization *.	0.851458 *	0.871669 *
MORT–30–HF ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure *.	0.881794 *	0.903985 *
MORT–30–PN ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization *.	0.882986 *	0.908124 *
Efficiency and Cost Reduction Measure			
MSPB–1 *	Payment-Standardized Medicare Spending per Beneficiary.	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.
± Previously adopted performance standards.

Comment: Several commenters noted that hospitals need timelier, more comprehensive and more coordinated data support from CMS, especially for claims measures, to better understand measure performance and how performance affects payments (for example, to model payment impacts). These commenters recommended that CMS release quarterly data sets that have sufficient information for hospitals to be able to track their performance on the Hospital VBP Program and understand the details of the program.

Response: We thank the commenters for the suggestions and will take this under advisement as we seek to make our measures more transparent. We currently release data annually, and we offer educational sessions for hospitals to learn more about policies and ask questions. Hospitals can learn more about such events by visiting: *http://www.qualityreportingcenter.com/inpatient/iqr/events/*.

Based on public comments in the FY 2015 IPPS/LTCH PPS final rule, we proposed to adopt the ''normalization'' approach to scoring the PCCEC/CC domain, which will introduce only minor changes to the original scoring formula, as follows. For purposes of the HCAHPS Base Score, the new CTM–3 dimensions would be calculated in the same manner as the eight existing HCAHPS dimensions. For each of the nine dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) would be calculated, the larger of which would be summed across the nine dimensions to create a prenormalized HCAHPS Base Score (0–90 points, as compared to 0–80 points when only eight dimensions were included). The prenormalized HCAHPS Base Score would then be multiplied by 8/9 (0.88888) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the nine dimensions would be of equal weight, so that, as before, the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points would then be calculated in the same manner as before and would continue to range from 0 to 20 points. The Consistency Points would now consider scores across all nine of the

PCCEC/CC dimensions. The final element of the scoring formula would be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points and will range from 0 to 100 points, as before.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2018 PROGRAM YEAR PATIENT AND CAREGIVER-CENTERED EXPERIENCE OF CARE/CARE COORDINATION DOMAIN

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	55.27	78.52	86.68
Communication with Doctors	57.39	80.44	88.51
Responsiveness of Hospital Staff	38.40	65.08	80.35
Pain Management	52.19	70.20	78.46
Communication about Medicines	43.43	63.37	73.66
Hospital Cleanliness & Quietness	40.05	65.60	79.00
Discharge Information	62.25	86.60	91.63
3-Item Care Transition *	25.21	51.45	62.44
Overall Rating of Hospital	37.67	70.23	84.58

* Newly proposed measure.

We invited public comments on these proposed performance standards.

Comment: One commenter supported the proposal to adjust the scoring of the HCAHPS measure to reflect the addition of a ninth dimension.

Response: We thank the commenter for its support.

Comment: One commenter expressed concern with how consistency points are calculated for the HCAHPS since such scores can reward both good and bad performance (for example, consistently good or consistently bad). The commenter recommended that CMS consider using a threshold such as 25th percentile, rather than a consistency score.

Response: As previously discussed, consistency points only reward performance that is consistently good across the HCAHPS dimensions. Consistently poor performance does not earn consistency points. Consistency points provide additional incentives beyond achievement and improvement points to improve a hospital's lowest-performing dimension.

After consideration of the public comments we received, we are finalizing the performance standards for the FY 2018 program year as proposed.

d. Previously Adopted Performance Standards for Certain Measures for the FY 2019 Program Year

As discussed above, we have adopted certain Safety and Clinical Care domain measures 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 2015 IPPS/LTCH PPS final rule (79 FR 50062 through 50065), we adopted the PSI–90 measure in the Safety domain and the THA/TKA measure in the Clinical Care domain for the FY 2019 program year. As with the PSI–90, MSPB–1, and NHSN measures described above, the THA/TKA measure is calculated with lower values representing better performance. Therefore, in the FY 2015 IPPS/LTCH PPS final rule we adopted the following performance standards for the FY 2019 program year (79 FR 50077):

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR CERTAIN SAFETY AND CLINICAL CARE DOMAIN MEASURES FOR THE FY 2019 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
Safety Measures			
PSI–90 *	Patient Safety for Selected Indicators (Composite)	0.853715	0.589462
Clinical Care Measures			
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization.	0.850671	0.873263
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization.	0.883472	0.908094
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0.882334	0.909460
THA/TKA *	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty.	0.032229	0.023178

* Lower values represent better performance.

e. Previously Adopted and Newly Adopted Performance Standards for Certain Measures for the FY 2020 Program Year

As discussed above, we have adopted certain Safety and Clinical Care domain measures 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 2015 IPPS/LTCH PPS final rule (79 FR 50063 through 50065), we adopted the PSI–90 measure in the Safety domain and the THA/TKA measure in the Clinical Care domain for the FY 2019 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50077), we also adopted the following performance standards for the MORT–30–AMI, MORT–30–HF, MORT–30–PN, and THA/TKA measures for the FY 2020 program year. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24507 through 24508), we proposed performance standards for the PSI–90 measure for the FY 2020 program year as set forth below:

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR CERTAIN CLINICAL CARE DOMAIN AND SAFETY DOMAIN MEASURES FOR THE FY 2020 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
Safety Domain			
PSI–90 *	Patient Safety for Selected Indicators (Composite)	0.778761	0.545903
Clinical Care Domain			
MORT–30–AMI ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization.	0.853715	0.875869
MORT–30–HF ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization.	0.881090	0.906068
MORT–30–PN ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0.882266	0.909532
THA/TKA * ±	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty.	0.032229	0.023178

* Lower values represent better performance.
± Previously adopted performance standards.

We did not receive any public comments on this proposal, and we are finalizing the performance standards as proposed.

f. Performance Standards for Certain Measures for the FY 2021 Program Year

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24508), we proposed the following performance standards for the FY 2021 program year for the Clinical Care domain measures (THA/TKA, MORT–30–HF, MORT–30–AMI, MORT–30–PN, and the proposed MORT–30–COPD):

PROPOSED PERFORMANCE STANDARDS FOR CLINICAL CARE DOMAIN MEASURES FOR THE FY 2021 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
Clinical Care Measures			
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Hospitalization.	0.860355	0.879714
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization.	0.883803	0.906144
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0.886443	0.91067
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization.	0.860355	0.879714
THA/TKA *	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty/Total Knee Arthroplasty.	0.03089	0.022304

* Lower values represent better performance.

We did not receive any public comments on this proposal, and we are finalizing the performance standards as proposed.

8. FY 2018 Program Year Scoring Methodology

a. Domain Weighting for the FY 2018 Program Year for Hospitals That Receive a Score on All Domains

In the FY 2015 IPPS/LTCH PPS final rule, we adopted the following domains and domain weights for the FY 2017 program year for hospitals that receive a score in all newly aligned domains:

DOMAIN WEIGHTS FOR THE FY 2017 PROGRAM YEAR FOR HOSPITALS RECEIVING A SCORE ON ALL DOMAINS

Domain	Weight (percent)
Safety	20
Clinical Care	30
• Clinical Care—Outcomes	• 25
• Clinical Care—Process	• 5
Efficiency and Cost Reduction	25
Patient and Caregiver-Centered Experience of Care/Care Coordination	25

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24498 through 24499), for the FY 2018 program year, we proposed to remove two ''topped-out'' measures from the Clinical Care—Process subdomain. In addition, we proposed to move one measure (PC–01) from the Clinical Care—Process subdomain to the Safety domain and to remove the Clinical Care—Process subdomain (80 FR 24500).

We stated that if these proposals are adopted, the Safety domain will include seven measures for the FY 2018 program year, including PC–01, which would be new to that domain. Because we proposed to move one measure to the Safety domain, and because we continue to believe that hospitals should be provided strong incentives to perform well on measures of patient safety, we proposed to increase the Safety domain's weight by 5 percentage points. We proposed to adopt the following FY 2018 program year domain weighting for hospitals receiving a score on all newly-aligned domains:

PROPOSED DOMAIN WEIGHTS FOR THE FY 2018 PROGRAM YEAR FOR HOSPITALS RECEIVING A SCORE ON ALL DOMAINS

Domain	Weight (percent)
Safety	25
Clinical Care	25
Efficiency and Cost Reduction	25
Patient and Caregiver-Centered Experience of Care/Care Coordination	25

We invited public comments on the proposed domain weights.

Comment: Several commenters supported CMS' proposal to reweight the four measure domains so that each accounts for 25 percent of a hospital's TPS. One commenter noted that the proposed equal weighting aligns with the CMS Quality Strategy and highlights the importance of each of the domains to understanding the value provided by a hospital caring for a patient.

Response: We thank the commenters for their support.

Comment: One commenter supported the proposal to increase the Safety domain's weight by five percent because of the addition of the PC–01 measure and our goal of providing strong incentives to hospitals to perform well on measures of patient safety.

Response: We thank the commenter for the support.

Comment: Several commenters supported the proposed updates to the scoring methodology, including the consolidation of the Clinical Care domain because the commenter noted that with our focus on clinical outcomes, it is less necessary for us to differentiate domain weights for outcome versus process measures.

Response: We thank the commenters for their support.

Comment: One commenter recommended that, in order to accurately score hospitals on their performance, CMS consider temporarily reducing the weight assigned to the Clinical Care measurement domain absent a plan to improve or replace the mortality measures due to concerns about their reliability. The commenter also recommended that CMS increase the weight of the Safety domain given that it is comprised of more reliable HAI measures.

Response: The mortality measures in the Hospital VBP Program have been tested for validity and reliability. While we agree that the Hospital VBP Program should encourage providers to improve patient outcomes, we believe that equally weighting the four domains is appropriate for the FY 2018 program year based on the distribution of the measures we are finalizing in this final rule. For the FY 2018 program year, we finalized seven measures for the Safety domain. We finalized three measures for the Clinical Care domain. We finalized one measure for the PCCEC/CC domain. We finalized one measure for the Efficiency and Cost Reduction domain.

Comment: A few commenters proposed that CMS weight the Safety and Clinical Care domains more heavily and give less weight to Efficiency and Cost Reduction and PCCEC/CC domains because hospitals have the greatest ability to effect change in the Safety and Clinical Care domains. One commenter recommended that the weights for the four domains be set at 20 percent for PCCEC/CC and Efficiency and Cost Reduction and at 30 percent for Safety and Clinic Care.

Response: We believe that hospitals can effect change through the measures in each of the four domains in the Hospital VBP Program. We believe that equally weighting the four domains is appropriate for the FY 2018 program year based on the distribution of the measures we are finalizing in this rule. For the FY 2018 program year, we finalized seven measures for the Safety domain. We finalized three measures for the Clinical Care domain. We finalized one measure for the PCCEC/CC domain. We finalized one measure for the Efficiency and Cost Reduction domain.

Comment: One commenter suggested that CMS raise the proposed weight of the Clinical Care domain to ensure that the focus of the Hospital VBP Program is on improved patient outcomes.

Response: While we agree that the Hospital VBP Program should encourage providers to improve patient outcomes, we believe that equally weighting the four domains is appropriate for the FY 2018 program year based on the distribution of the measures we are finalizing in this final rule. For the FY 2018 program year, we finalized seven measures for the Safety domain. We finalized three measures for the Clinical

Care domain. We finalized one measure for the PCCEC/CC domain. We finalized one measure for the Efficiency and Cost Reduction domain.

Comment: Several commenters recommended other scoring options such as scoring statistical outliers differently compared to those that are clustered around the mean or lowering the achievement threshold so that hospitals have greater potential to attain achievement points. One commenter proposed that CMS acknowledge that maximum achievement points are not possible for all outcome measures and that CMS should review how these measures are scored in the future.

Response: We thank commenters for their recommendation with regard to the statistical outliers, and we will take it into consideration for future rulemaking. We disagree with the commenter's assertion that maximum achievement points are not possible for all outcome measures. We refer the commenter to the Hospital Inpatient VBP Program final rule (76 FR 26514) where we adopted a methodology for scoring outcome measures. We note that if a hospital's performance on an outcome measure during a performance period is greater than or equal to the benchmark, the hospital receives the maximum 10 achievement points. While we acknowledge the commenter's concerns regarding the potential to achieve maximum achievement points, we also note that the benchmark is intended to represent a level of excellent performance to which hospitals generally should aspire.

Comment: A few commenters expressed concern that the scoring methodology could allow hospitals that achieve low cost care at low quality to also receive incentive payments, or at least not be penalized, because there is no penalty component to providing poor quality care. One commenter suggested that CMS assist poor performing hospitals by helping them identify how to make appropriate changes for positive results. The commenter also urged CMS to ensure that hospitals are unable to mask poor care for some patient populations while providing high quality care to others.

Response: We acknowledge the commenters' concerns and encourage all hospitals unsure of how to improve their performance, on any measure finalized for the Hospital VBP Program, to utilize the quality improvement resources that CMS, AHRQ, and CDC have made available to assist hospitals with improvement (QIOs, QI toolkits, PSOs, and NHSN State-based prevention initiatives). We also offer an improvement Webinar series where hospitals with high levels of achievement share their path to improvement. We encourage stakeholders to subscribe to our listserv titled ''Hospital Inpatient Value-Based Purchasing (HVBP) and Improvement'' to receive notification of scheduled events. *https://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic/ListServe/Register*.

Comment: A few commenters did not support the weight given to the Efficiency and Cost Reduction domain, which consists of just the MSPB–1 measure because they believed that this weight was disproportionately heavy. One commenter noted that hospitals are unable to monitor their own performance. Another commenter believed that measuring Medicare payments will not lead to quality improvements.

Response: As we stated in the FY 2014 IPPS/LTCH PPS final rule (79 FR 50048 through 50087), we believe we have appropriately balanced our desire to provide strong incentives for hospitals to consider the cost and the quality of the care that they provide to Medicare beneficiaries and to all patients by assigning the Efficiency and Cost Reduction domain to 25 percent of the TPS. We continue to believe it merits significant domain weighting in order to ensure that hospitals monitor the costs of the care they provide to Medicare beneficiaries during the inpatient hospitalization and are involved in the coordination of beneficiaries' care immediately prior to a hospitalization and post-discharge.

With regard to the concern that the domain is comprised of only one measure, we acknowledge the potential for building a more robust efficiency measure set, as we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53585 through 53586) and FY 2014 IPPS/LTCH PPS final rule (79 FR 50048 through 50087). In the FY 2015 IPPS/LTCH PPS rulemaking (79 FR 28122 through 28224; 79 FR 50066 through 50070), we sought comment on measures that could potentially be used to expand the Efficiency and Cost Reduction domain in the future. We also again solicited and received public comments on how we might pursue that goal in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24503). In the interim, we continue to believe that increased emphasis on efficiency is an important goal for the Hospital VBP Program, and that the efficiency domain weight should remain at 25 percent accordingly. However, we thank the commenters for their thoughts and intend to continue examining domain weighting and will consider revisiting this issue in the future.

Comment: Some commenters did not support CMS' proposal to adopt equal weighting across all four domains because of the overlap of measures in the Hospital VBP Program and other reporting programs.

Response: While we acknowledge that there is some overlap in quality measures between the Hospital VBP Program and the HAC Reduction Program, we note that these measures cover topics of critical importance to quality improvement and patient safety in the inpatient hospital setting. We selected these quality measures because we believe that HAC measures comprise some of the most critical patient safety areas. These measures track infections that could cause significant health risks to Medicare beneficiaries, and we believe it is appropriate to provide incentives for hospitals to avoid them under more than one program.

We further stress that the HAC Reduction Program and the Hospital VBP Program are separate programs with different purposes and policy goals. The HAC Reduction Program reduces payments to hospitals for excess hospital acquired conditions to increase patient safety in hospitals. On the other hand, the Hospital VBP Program is an incentive program that redistributes a portion of the Medicare payments made to hospitals based on their performance on various measures. Therefore, although the measures exist in more than one program, the measures are used and calculated for very distinct purposes. Accordingly, we believe that the critical importance of these measures to patient safety warrants their inclusion in both programs. We will, in the future, continue to monitor the HAC Reduction Program and Hospital VBP Program 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.

After consideration of the public comments we received, we are finalizing the domain weights as proposed.

b. Domain Weighting for the FY 2018 Program Year for Hospitals Receiving Scores on Fewer Than Four Domains

In prior program years, we finalized a policy that hospitals must have received domain scores on all finalized domains in order to receive a TPS. However, because the Hospital VBP Program has evolved from its initial two domains to an expanded measure set with additional domains, we considered whether it was appropriate to continue this policy.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53606 through 53607), we finalized our proposal that, for the FY 2015 program year and subsequent years, hospitals with sufficient data to receive at least two out of the four domain scores that existed for the FY 2015 program year (that is, sufficient cases and measures to receive a domain score on at least two domains) will receive a TPS. We also finalized our proposal that, for hospitals with at least two domain scores, TPSs would be reweighted proportionately to the scored domains to ensure that the TPS is still scored out of a possible 100 points and that the relative weights for the scored domains remain equivalent to the weighting which occurs when there are scores in all four domains. We believe that this approach allows us to include relatively more hospitals in the Hospital VBP Program while continuing to focus on reliably scoring hospitals on their quality measure performance.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50701 through 50702), we continued this approach for the FY 2016 program year and subsequent program years for purposes of eligibility for the program.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085), we adopted a policy that, for the FY 2017 program year and subsequent years, hospitals must receive domain scores on at least three quality domains in order to receive a TPS. We stated our belief that, by adopting this policy, we will continue to allow as many hospitals as possible to participate in the program while ensuring that reliable TPSs result. We also finalized a policy that hospitals with sufficient data on at least three of four domains for FY 2017 will have their TPSs proportionately reweighted. Finally, in the FY 2015 IPPS/LTCH PPS final rule, we adopted case minimums for the FY 2016 program year and subsequent years (79 FR 50085 through 50086).

Under these policies, in order to receive a TPS for the FY 2018 program year:

- Hospitals must meet the requirements to receive an HCAHPS Survey measure score in order to receive a PCCEC/CC domain score. Hospitals must report a minimum number of 100 HCAHPS surveys for a hospital to receive a PCCEC/CC domain score (76 FR 26530).
- Hospitals must meet the requirements to receive a MSPB–1 measure score in order to receive an Efficiency and Cost Reduction domain score. Hospitals must report a minimum number of 25 cases for the MSPB–1 measure (77 FR 53609 through 53610).
- Hospitals must receive a minimum of two measure scores within the Clinical Care domain. Hospitals must report a minimum number of 25 cases for each of the mortality measures (77 FR 53609 through 53610).
- Hospitals must receive a minimum of three measure scores within the Safety domain.

++ Hospitals must report a minimum of three cases for any underlying indicator for the PSI–90 measure based on AHRQ's measure methodology (77 FR 53608 through 53609).

++ Hospitals must report a minimum of one predicted infection for NHSN-based surveillance measures based on CDC's minimum case criteria (77 FR 53608 through 53609).

++ Hospitals must report a minimum of 10 cases for the PC–01 measure (76 FR 26530).

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24509), we did not propose any changes to the minimum numbers of cases and measures that we have adopted above. However, because we proposed to remove the Clinical Care—Process subdomain from the Hospital VBP Program effective with the FY 2018 program year, we considered whether we should revisit our finalized requirement that hospitals must receive scores on at least three domains in order to receive a TPS. However, we continue to believe that this requirement appropriately balances our desire to enable as many hospitals as possible to participate in the Hospital VBP Program and the need for TPSs to be sufficiently reliable to provide meaningful distinctions between hospitals' performance on quality measures. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24509), we did not propose to change this requirement at that time. We welcomed public comments on whether we should consider adopting a different policy on this topic. We indicated that we will continue to proportionately reweight hospitals' TPSs when they have sufficient data on only three domains.

We did not receive any public comments on this issue.

G. Changes to the Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to section V.I.1.a. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program.

2. Statutory Basis for the HAC Reduction Program

Section 3008 of the Affordable Care Act added section 1886(p) to the Act to provide an incentive for certain hospitals to reduce the incidence of HACs. Section 1886(p) of the Act requires the Secretary to make an adjustment to payments to ''applicable hospitals'' effective beginning on October 1, 2014, and for subsequent program years. Section 1886(p)(1) of the Act sets forth the requirements by which payments to ''applicable hospitals'' will be adjusted to account for HACs with respect to discharges occurring during FY 2015 or later. For hospitals with HAC scores in the top quartile relative to other applicable hospitals for a given fiscal year, the amount of Medicare payment is reduced to 99 percent of the amount of payment that would otherwise apply to discharges under section 1886(d) or 1814(b)(3) of the Act, as applicable. Section 1886(p)(2)(A) of the Act defines ''applicable hospitals'' as subsection (d) hospitals that meet certain criteria. Section 1886(p)(2)(B)(i) of the Act defines these criteria and specifies that the payment adjustment would apply to an applicable hospital that ranks in the top quartile (25 percent) of all subsection (d) hospitals, relative to the national average, of conditions acquired during the applicable period, as determined by the Secretary. Section 1886(p)(2)(B)(ii) of the Act requires the Secretary to establish and apply a risk-adjustment methodology in calculating HAC scores for each hospital.

Sections 1886(p)(3) and (p)(4) of the Act define ''hospital-acquired conditions'' and ''applicable period,'' respectively. The term ''hospital-acquired condition'' means ''a condition identified in subsection 1886(d)(4)(D)(iv) of the Act and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital, as determined by the Secretary.'' The term ''applicable period'' means, with respect to a fiscal year, a period specified by the Secretary.

Section 1886(p)(5) of the Act requires that, prior to FY 2015 and each subsequent fiscal year, the Secretary provide confidential reports to each applicable hospital with respect to the HAC Reduction Program scores for the applicable period, to give the hospitals an opportunity to review and correct the data. Section 1886(p)(6)(A) of the Act sets forth the reporting requirements by which the Secretary would make information available to the public regarding HACs for each applicable hospital. Section 1886(p)(6)(B) of the Act requires the Secretary to ensure that an applicable hospital has the opportunity to review, submit corrections, and for the information to

be made public with respect to the HAC scores of the applicable hospital prior to such information being made public. Section 1886(p)(6)(C) of the Act requires that, once corrected, the HAC scores be posted on the *Hospital Compare* Web site (*http://www.medicare.gov/hospitalcompare/search.html*) in an easily understandable format.

Section 1886(p)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(p) of the Act. These determinations include: what qualifies as an applicable hospital; the specifications of a HAC; the Secretary's determination of the ''applicable period''; the provision of confidential reports submitted to the applicable hospital; and the information publicly reported on the *Hospital Compare* Web site.

3. Overview of Previous HAC Reduction Program Rulemaking

For further description of our policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104). These policies describe the general framework for implementation of the HAC Reduction Program, including: (a) The relevant definitions applicable to the program; (b) the payment adjustment under the program; (c) the measure selection and conditions for the program, including a risk-adjustment and scoring methodology; (d) performance scoring; (e) 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 (f) limitation of administrative and judicial review.

We have also codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

4. Implementation of the HAC Reduction Program for FY 2016

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24509 through 24514), we did not propose any changes to the above described policies for the implementation of the HAC Reduction Program for FY 2016. However, we remind readers that, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50101 through 50102), we finalized the following measures for use in the FY 2016 program: AHRQ PSI–90 Composite and CDC Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), and Colon and Abdominal Hysterectomy Surgical Site Infection (SSI). In the FY 2016 IPPS/LTCH PPS proposed rule, we did not propose to add or remove any measures for FY 2016.

We provided an update on NQF proceedings for three of the measures previously finalized for the FY 2016 program: PSI–90 Composite; CLABSI; and CAUTI. For FY 2016, we are retaining the AHRQ PSI–90 Composite measure (in Domain 1) that we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717). As we noted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50090), the AHRQ PSI–90 Composite measure is undergoing NQF maintenance review. At the time of development of this final rule, the PSI–90 Composite measure consists of eight component indicators: PSI–3 Pressure ulcer rate; PSI–6 Iatrogenic pneumothorax rate; PSI–7 Central venous catheter related blood stream infections rate; PSI–8 Postoperative hip fracture rate; PSI–12 Perioperative pulmonary embolism or Deep vein thrombosis rate; PSI–13 Postoperative sepsis rate; PSI–14 Postoperative wound dehiscence rate; and PSI–15 Accidental puncture or laceration rate.

As part of the NQF maintenance review process, AHRQ is considering revisions to the composite weighting system as well as the addition of PSI–9 Perioperative hemorrhage rate, PSI–10 Postoperative physiologic and metabolic derangement rate, and PSI–11 Postoperative respiratory failure rate measures, or a combination of these three measures, to the PSI–90 Composite measure. We consider the potential inclusion of additional component measures in the PSI–90 Composite measure to be a significant change to the measure and, if that occurs, we would engage in notice-and-comment rulemaking prior to requiring the reporting of the revised composite for the HAC Reduction Program. At the time of development of this final rule, the AHRQ PSI–90 Composite measure is continuing to undergo NQF maintenance review. No changes have been finalized. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24510), we did not propose any changes to this measure.

Similarly, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50090), we noted that the CDC NHSN CAUTI and CLABSI measures in Domain 2 that we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717) for inclusion in FYs 2015, 2016, and 2017 were undergoing NQF maintenance review. We stated in the FY 2015 IPPS/LTCH PPS final rule that if there are significant changes to these measures, we would engage in notice-and-comment rulemaking prior to requiring the reporting of the revised measures. These measures have now completed the NQF maintenance review process, and modified versions of the measures were reendorsed by NQF on November 10, 2014.[108] We note that reendorsed versions of the CDC NHSN CLABSI and CAUTI measures included a new statistical option for calculating the measure result, the Adjusted Ranking Metric (ARM), in addition to the standardized infection ratio (SIR) statistical option. For FY 2016, we will continue use of the CDC NHSN CLABSI and CAUTI measures as previously finalized for the program with use of the SIR. We will be working with CDC in the future to determine if the newly available ARM would be appropriate for use in the HAC Reduction Program. If we determine at a later time that the ARM is appropriate for use in the HAC Reduction Program and provides an advantage to the existing measure result (the SIR), we would propose this change in notice-and-comment rulemaking.

We noted in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24511) that we anticipated providing hospitals with their confidential hospital-specific reports and discharge level information used in the calculation of their FY 2016 Total HAC Score in late summer 2015 via the *QualityNet Secure Portal.*[109] In order to have access to their hospital-specific reports, hospitals must register for a *QualityNet Secure Portal* account. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24511), we did not propose to make any changes to the review and correction policies for FY 2016. Hospitals have a period of 30 days after the information is posted to the *QualityNet Secure Portal* to review and submit corrections for the calculation of their HAC Reduction Program measure scores, domain scores, and Total HAC Score for the fiscal year.

Comment: Some commenters supported the HAC Reduction Program because they believe it serves as a mechanism against preventable and adverse events and effectively promotes improvement in hospitals.

Response: We appreciate the commenters' support. We are committed to the reduction of HACs, which are important markers of quality of care and

[108] National Quality Forum. Measures search. Available at: *http://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=1122&print=0&entityTypeID=1* and *http://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=1121&print=0&entityTypeID=1.*

[109] Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598.*

whose reduction can possibly influence patient outcomes and the cost of care.

Comment: Some commenters expressed concerns about the threshold levels for penalties and argued that the program overwhelmingly and disproportionately penalizes the nation's major teaching hospitals. The commenters stated that hospitals are identified as poor performers due to limitations in the scoring methodology, data collection, risk adjustment, and size of teaching facilities, rather than to true differences in the quality of care. These commenters noted that hospitals that have instituted rigorous programs to identify and treat infections are at a disadvantage when compared to those with less comprehensive quality programs. The commenters suggested that CMS explore measure performance within specific hospital peer cohorts to allow hospitals to be compared based on similar characteristics and risk profiles.

Response: We acknowledge the commenters' concerns. We note that the intent of the HAC Reduction Program is to encourage all hospitals to reduce the incidence of HACs, and that there is room for improvement in the incidence of HACs, regardless of the institution or hospital. The measures adopted in the HAC Reduction Program, which are risk-adjusted to ensure that hospitals serving a large proportion of sicker patients will not be penalized unfairly, target important quality improvement areas. Endorsement by the NQF and support by the NQF MAP also are taken into account in deciding which measures to adopt. All of the measures finalized for inclusion in the HAC Reduction Program are NQF-endorsed and were recommended for inclusion in the program by the NQF MAP. We believe that the HAC Reduction Program encourages improvement in patient safety over the long term for all hospitals. We will continue to monitor the HAC Reduction Program and take the commenters' concerns under consideration as we strive to improve the program.

Comment: Some commenters urged CMS to use administrative authority under section 1886(d)(5)(I)(i) of the Act to limit the HAC penalty to the base operating DRG payment only, which they believed would be consistent with Congressional intent and with the Hospital VBP Program and the Hospital Readmissions Reduction Program. The commenters noted that, by restricting the penalty to the base operating DRG payment only, CMS could ensure consistency across our value-based purchasing programs and reduce provider confusion.

Response: We did not propose to change the application of the payment adjustment that we finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50711). As we discussed in that rule, the statutory requirements for the HAC Reduction Program payment adjustment differ from those for the Hospital VBP Program and the Hospital Readmissions Reduction Program. In accordance with sections 1886(o)(7)(A) and 1886(o)(7)(B) of the Act, the Hospital VBP Program applies adjustments to the base operating DRG payment amount, which is defined at section 1886(o)(7)(D) of the Act to exclude certain payments under subsection (d). Similarly, in accordance with section 1886(q)(1) of the Act, the Hospital Readmissions Reduction Program adjustment is applied to the base operating DRG payment amount, which is defined at section 1886(q)(2) of the Act to exclude certain payments under subsection (d).

For the HAC Reduction Program, no such statutory exclusion exists and section 1886(p)(1) of the Act states that the payment for applicable hospitals shall be equal to 99 percent of the amount of payment that would otherwise apply. Therefore, the HAC Reduction Program payment adjustment will continue to be applied after the application of the other program adjustments, including add-on payments consisting of outliers, DSH, uncompensated care, and IME. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (78 FR 50088) for additional information on the HAC Reduction Program's payment adjustment.

Comment: Some commenters suggested that CMS use the Adjusted Ranking Metric (ARM) option for calculating the measure results for the CDC NHSN CLABSI and CAUTI measures. The ARM is a summary measure calculation used to rank facilities and accounts for differences in the amount of exposure volume (that is, patient months, patient days, or device days) or opportunity for healthcare-associated infection among a group of patients in a given facility, as well as unmeasured variation across facilities. The commenters stated this would allow for an equal weighting between hospitals with low exposure volumes and hospitals with high exposure volumes.

Response: We thank commenters for this suggestion. We will be working with CDC in the future to determine if the newly available ARM would be appropriate for use in the HAC Reduction Program. If we determine at a later time that the ARM is appropriate for use in the HAC Reduction Program and provides an advantage to the existing measure result (the SIR), we would propose this change in notice-and-comment rulemaking.

Comment: Some commenters suggested that CMS institute appropriate sociodemographic status (SDS) adjustments for hospitals serving vulnerable patient populations.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk-adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: Numerous commenters expressed concerns about overlap in quality measures between the Hospital VBP Program and the HAC Reduction Program. The commenters argued that this overlap creates the possibility of double penalties for some hospitals, while assessing disparate scores on the same measures for other hospitals. The commenters suggested that CMS eliminate the measure overlap between the programs.

Response: As we stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50056), we acknowledge that there is

some overlap in quality measures between the Hospital VBP Program and the HAC Reduction Program. While we are aware that commenters object to scoring hospitals on certain measures under both programs, we note that these measures cover topics of critical importance to quality improvement in the inpatient hospital setting and to patient safety. We selected these quality measures because we believe that HAC measures comprise some of the most critical patient safety areas. These measures track infections that could cause significant health risks to Medicare beneficiaries, and we believe it is appropriate to provide incentives for hospitals to avoid them under more than one program. Patient safety is a CMS priority and we believe justifies the use of the measures in both programs.

We further note that the HAC Reduction Program and the Hospital VBP Program are separate programs with different purposes and policy goals. The HAC Reduction Program is a program that reduces payments to hospitals for excess HACs to increase patient safety in hospitals. On the other hand, the Hospital VBP Program is an incentive program that redistributes a portion of the Medicare payments made to hospitals based on their performance on various measures. Therefore, although the measures exist in more than one program, the measures are used and calculated for very distinct purposes. Accordingly, we believe that the critical importance of these measures to patient safety warrants their inclusion in both programs. We will, in the future, monitor the HAC Reduction Program and the Hospital VBP Program 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 warranted.

Comment: Numerous commenters raised concerns about the current inclusion of the PSI–90 Composite measure in the HAC Reduction Program. The commenters argued that a number of the measures in the PSI–90 Composite are rare events and do not meet the high-volume requirement for measures in the HAC Reduction Program. The commenters suggested that CMS only include measures that accurately gauge quality and are not inherently skewed against teaching hospitals, large hospitals, and hospitals that provide care to vulnerable populations. The commenters suggested that CMS review alternatives to the PSI–90 Composite, given the concerns raised by the NQF committee and the resulting nonendorsement of the measure during the maintenance review process last year. The commenters noted that this is a composite measure and it would be more informative for consumers to utilize separate public safety measures.

Response: We would like to clarify the status of the PSI–90 Composite measure with regard to NQF endorsement; the PSI–90 Composite measure has not lost NQF endorsement but still remains under maintenance review. As part of the routine NQF measure maintenance process, the Patient Safety Committee expressed concerns about the weighting of the PSI–90 measure components and requested to see additional measure information related to reweighting of the PSI–90 Composite measure with the three additional components (PSI–9, PSI 10, and PSI–11) before deciding if it would recommend continued endorsement of the measure. AHRQ has submitted the requested data for the NQF Patient Safety Committee's consideration. In regard to commenters' concerns regarding the validity of the PSI–90 Composite measure, we note that NQF has previously endorsed the PSI–90 Composite as a valid measure (NQF #0531). We continue to believe the PSI–90 Composite is an important measure of patient safety. Experts agree that this measure is scientifically rigorous. In regard to the administrative data elements of the PSI–90 Composite measure, we note that there are previously conducted validation studies that validate the relationship between administrative claims data and medical records. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50091) for a further discussion of the validation of the relationship between administrative claims data and medical records.

Comment: One commenter argued the current PSI–90 Composite measure components have been demonstrated to have low measure validity and rely heavily on administrative data elements. The commenter noted that some codes, like sepsis, have a wide variation in the documentation and assignment of the diagnosis and that, by manipulating the diagnosis, it is possible to change the performance rates of this measure without actually affecting the care of the patient. The commenter recommended that CMS implement a policy to improve the validity of these claim-based measures. Specifically, the commenter proposed that the policy should:

- Require hospitals to make an annual attestation that they are explicitly following specific coding and documentation practices, as outlined by professional organizations such as the Association for Clinical Documentation Improvement Specialists (ACDIS) and American Health Information Management Association (AHIMA);
- Release joint consensus statements in collaboration with AHIMA, ACDIS, and Coding Clinics to provide clarity to hospitals around codes that will include or exclude a case from claims-based measures;
- Require that hospitals maintain a record of codes that are changed as a result of internal coding reviews to provide a record for coding and documentation audits; and
- Conduct random and routine audits of these documentation and coding practices at the hospital level.

Response: We have previously addressed the commenters' specific concerns regarding validity and coding issues of the PSI–90 Composite measure, and we refer readers to our responses to these comments in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50715). We acknowledge the commenters' continuing concerns and will continue to monitor the use of this measure in the HAC Reduction Program.

Comment: Some commenters supported the addition of the PSI–11, Postoperative Respiratory Failure Rate measure component, pending testing. The commenters noted that postoperative respiratory failure is a condition for which actionable guidelines exist, with evidence-based screening criteria to determine what individuals are at risk. However, the commenters disagreed with the inclusion of both PSI–9, Perioperative Hemorrhage Rate and PSI–10, Postoperative Physiologic and Metabolic Derangement Rate. One commenter noted its experience with high false positive rates for both measures. This commenter cited complaints from physicians due to unclear coding criteria, resulting in the code being used too frequently and inconsistently.

Response: We appreciate commenters' input and acknowledge their concerns. We are aware that NQF is reviewing the PSI–90 Composite measure with three additional components (PSI–9, PSI–10, and PSI–11), as part of the routine measure maintenance process. We will take NQF's decision on continuing endorsement into consideration when evaluating whether the measure remains appropriate for the HAC Reduction Program. In regard to commenters' concerns regarding the validity of the PSI–90 Composite measure, we note that NQF has previously endorsed the PSI–90 Composite as a valid measure (NQF #0531). We continue to believe

the PSI–90 Composite is an important measure of patient safety.

Comment: Several commenters noted that perioperative hemorrhage is a high-volume condition and that up to 5 percent of patients who undergo cardiac surgery require additional surgery to control bleeding. The commenters also noted that postoperative respiratory failure is also a high-cost condition. The commenters stated that perioperative hemorrhage and postoperative respiratory failure are preventable conditions by the use of evidence-based guidelines. The commenters suggested that, pending NQF endorsement of the addition of these measures, CMS expeditiously incorporate these measures through rulemaking. The commenters also supported CMS' commitment to pursue the changes to the HAC Reduction Program through rulemaking.

Response: We appreciate the commenters' input and will take this feedback into consideration in future measure selection and rulemaking. We emphasize that improving patient safety is our primary objective for the HAC Reduction Program. AHRQ's Quality Indicator program continually updates and refines measures to provide the best possible quality indicators to the public. All of the AHRQ quality indicators go through a rigorous testing process prior to changes being made to the indicators. We note that NQF policy and guidance generally has favored risk adjustment approaches over exclusion of high-risk patients, when possible, to optimize the generalizability and value of quality measures. Suggestions regarding potential PSI measure revisions can be made directly to *QIsupport@ahrq.hhs.gov*.

Comment: One commenter expressed concerns with the unintended consequence of the CDC Surgical Site Infection (SSI) measure. The commenter noted that this measure is disproportionately skewing and penalizing SSI rates in large tertiary centers that perform exenterations, especially for recurrent cancers. The commenter noted that exenterations are rare, complex multi-organ system resections and are performed for one of three reasons: colorectal cancer, a genitourinary (GU) cancer, or a gynecologic cancer. The commenter stated that the few institutions that perform these rare operations might be disproportionately affected by misclassification of SSIs in cases of recurrent cancer when the colon has previously been removed and only the small bowel is included as the gastrointestinal component of the exenteration. The commenter suggested that the unintended consequence could be remedied by a new CPT code for exenteration for recurrent cancer including small bowel sans colon, or exclusion of exenteration from NQF #0753.

Response: We are using the SSI measure in the HAC Reduction Program as specified by the measure steward, the CDC. Comments and suggestions regarding inclusion and exclusion criteria should be addressed to *NHSN@cdc.gov*. We appreciate and are concerned about unintended consequences and will continue to monitor the HAC Reduction Program and take the commenters' concerns under consideration.

Comment: One commenter suggested that CMS identify untreated malnutrition, including disease-related malnutrition (acute and chronic) as a HAC. The commenter noted that including untreated malnutrition would encourage hospitals to implement policies and procedures that promote systematic nutrition screening, assessment, and appropriate nutrition intervention. The commenter stated that it is widely recognized that nutritional status plays a significant role in health outcomes and healthcare costs. The commenter cited that malnourished patients are more likely to experience complications such as pneumonia, pressure ulcers, nosocomial infections, and death. The commenter also cited that malnourished patients have significantly longer hospitalizations. The commenter stated the inclusion of untreated malnutrition would create the necessary accountability to minimize the health and economic impact of disease-malnutrition.

Response: We thank the commenter for this suggestion and will consider new measures in the program through future rulemaking.

5. Changes for Implementation of the HAC Reduction Program for FY 2017

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the following measures for use in the FY 2017 program: AHRQ PSI–90 Composite and CDC NHSN CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia, and *Clostridium difficile* (CDI). In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24511), we did not propose any changes to this measure set for FY 2017. We also did not propose to make any changes to the measures from how they were finalized for use in the FY 2016 program (CAUTI, CLABSI, and Colon and Abdominal Hysterectomy SSI) or FY 2017 program (the addition of MRSA Bacteremia and CDI).

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24511 through 24512), for FY 2017, we proposed three changes to existing program policies: (1) The dates of the time period used to calculate hospital performance; (2) the addition of a narrative rule used in the methodology to calculate the Domain 2 score; and (3) the relative contribution of Domain 1 (patient safety) and Domain 2 (infection) to the Total HAC Score. Each proposal is described in more detail below.

a. Applicable Time Period for the FY 2017 HAC Reduction Program

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized and codified policy at 42 CFR 412.170 that provided that there will be a 2-year applicable time period to collect data used to calculate the Total HAC Score.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24511), for FY 2017, we proposed to continue similar 2-year time periods for the calculation of HAC Reduction Program measure results. For the Domain 1 measure (AHRQ PSI–90 Composite measure), we proposed to use the 24-month period from July 1, 2013 through June 30, 2015. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2017. For the CDC NHSN measures, previously finalized for use in the FY 2017 HAC Reduction Program (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we proposed to use data from CYs 2014 and 2015.

We sought public comment on the proposal to use these updated time periods for calculation of measure results for the FY 2017 program.

Comment: One commenter supported the proposed time periods for the calculation of HAC Reduction Program measure results. The commenter noted that this proposed change places an emphasis on outcome based measures, allowing for focus on influencing preventable events and improvement on quality of care.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing the proposed applicable time periods discussed above for the FY 2017 HAC Reduction Program without modification.

b. Narrative Rule Used in Calculation of the Domain 2 Score for the FY 2017 HAC Reduction Program

We noted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723) that there will be instances in which applicable hospitals may not have data on all Domain 1 and 2 measures, and, therefore, a set of narrative rules were finalized to determine how to score each Domain. The scoring rules were finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723 through 50725) and clarified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50096 through 50098). For FY 2017, we will follow the rules as previously finalized. As described below, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24511 through 24512), we also proposed an additional narrative rule for use beginning in the FY 2017 program year. This additional narrative rule would be applicable to calculation of the Domain 2 score and would treat each Domain 2 measure independently when determining if a score of 10 (maximal score) should be assigned to the measure for nonsubmission of data without a waiver (if applicable).

We note that the current narrative rules for Domain 2 assign a score for each Domain 2 measure and the measure scores are averaged to provide a Domain 2 Score. For the FY 2015 and FY 2016 HAC Reduction Program, if a hospital reports data for at least one of the Domain 2 measures, its Domain 2 Score is based solely on the measure(s) the hospital reported and the hospital is not assigned the maximum number of points for any nonreported measure(s). This approach was employed for the FY 2015 and FY 2016 HAC Reduction Program because the applicable periods for the Domain 2 measures for those program years (the FY 2015 period was January 1, 2012 through December 31, 2013, and the FY 2016 period was January 1, 2013 through December 31, 2014) occurred, at least in part, prior to the announcement of the HAC Reduction Program with the publication of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729) in August 2013. The proposed applicable period for Domain 2 measures in the FY 2017 program (CYs 2014 and 2015) occurs in its entirety after the HAC Reduction Program was announced. In the FY 2016 IPPS/LTCH PPS proposed rule, we informed hospitals of the impact that not reporting these data would have on their FY 2017 Total HAC Score. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24511 through 24512), we proposed, for FY 2017 and subsequent program years, that each Domain 2 measure be treated independently when determining if a score of 10 (maximal score) should be assigned to the measure for nonsubmission of data without a waiver (if applicable). For instance, if a hospital does not submit data for the Colon and Abdominal Hysterectomy SSI measure and does not have a valid waiver for nonreporting, the measure would receive a score of 10. This score of 10 would then be combined with the measure scores the hospital received for data reported on the other FY 2017 Domain 2 measures (CLABSI and CAUTI) to calculate the hospital's total Domain 2 score. The rationale for this proposed change in methodology is to encourage hospitals to submit all available data on all measures in the program and to further encourage hospitals to reduce all HACs included in the program.

We invited public comments on our proposal to implement the score calculations discussed above in FY 2017 and subsequent years, as well as our proposal for an additional narrative rule that would treat each Domain 2 measure independently when determining if a score of 10 (maximal score) should be assigned to the measure for nonsubmission of data without a waiver (if applicable).

Comment: Many commenters supported the proposed changes to the narrative rule used in the calculation of Domain 2 scores. The commenters noted that these proposed changes support greater transparency by encouraging hospitals to submit all available data required for reporting to NHSN on the different measures captured in the Domain 2 score. One commenter noted that, in December 2014, the technical expert panel (TEP) convened by CMS to reevaluate scoring methodology recommended treating Domain 2 measures independently for purposes of determining a Domain 2 score. Some commenters also suggested that, in addition to exempting those with waivers, CMS continue the practice of not calculating a score when data have been submitted but there is not enough data to calculate the standardized infection ratio (SIR). These commenters suggested that CMS clarify in the final rule that it will continue this practice.

Response: We appreciate the commenters' support. To provide clarification in this final rule, in the event the SIRs for each Domain 2 measure cannot be calculated because the facility has less than 1.0 predicted infection for each measure, a Domain 2 score cannot be calculated and so we will use solely the Domain 1 score to calculate a hospital's Total HAC Score. In other words, we will exclude from the Total HAC Score calculation any measure for which a SIR cannot be calculated.

Comment: Some commenters suggested that CMS amend the program to include only hospitals with enough data to report at least one of the infection measures in Domain 2. The commenters suggested that CMS consider an alternative scoring methodology for hospitals that do not have adequate data for Domain 2. The commenters also suggested that hospitals for which CMS is unable to calculate a Domain 2 score be excluded from the pool of hospitals that determine the penalty quartile.

Response: We acknowledge the commenters' concern and appreciate the suggestions. However, we note that section 1886(p)(2) of the Act requires all subsection (d) hospitals under the Act to be included in the HAC Reduction Program. In addition, the intention of the scoring methodology for calculating a Total HAC Score is to make use of all available data for each hospital and to encourage hospitals to report HAI data to CDC NHSN, even if they do not have enough data to reliably calculate a SIR for the CDC NHSN HAI measures in Domain 2. CDC indicated that it continuously evaluate the data reported to NHSN and consider the best measures for monitoring and comparative purposes.

After consideration of the public comments we received, we are finalizing the narrative rules used in the calculation of the Domain 2 Score discussed above as proposed.

c. Domain 1 and Domain 2 Weights for the FY 2017 HAC Reduction Program

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50102), we finalized for FY 2016 a methodology for calculating a Total HAC Score for each hospital by determining a score for each domain, then multiplying each domain score by a weight (Domain 1—AHRQ Patient Safety Indicators, 25 percent; Domain 2—CDC NHSN measures, 75 percent), and adding together the weighted domain scores to determine the Total HAC Score (§ 412.172(e)(3)).

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24512), for FY 2017, we proposed to adjust the weighting of Domains 1 and 2 so that the weight of Domain 1 would be 15 percent and the weight of Domain 2 would be 85 percent. We proposed to decrease the Domain 1 weight for two reasons. First, with the implementation of the CDC MRSA Bacteremia and CDI measures in the FY 2017 program, we believe the weighting of both domains

needs to be adjusted to reflect the addition of the fifth and sixth measures in Domain 2. Second, among the public comments on the FY 2014 and FY 2015 IPPS/LTCH PPS final rules that were considered, MedPAC and other stakeholders recommended that Domain 2 should be weighted more than Domain 1 because they believed the CDC NHSN chart-abstracted measures in Domain 2 were more reliable and actionable than claims-based measures. We invited public comments on this proposal to decrease the Domain 1 weight from 25 percent to 15 percent and increase the Domain 2 weight from 75 percent to 85 percent for FY 2017.

Comment: Many commenters supported the proposed adjustment to the relative weightings of Domains 1 and 2 for FY 2017. The commenters stated that the proposed change gives more weight to the CDC NHSN chart-abstracted measures, which utilize standardized definitions that capture both data on Medicare as well as non-Medicare patients, rather than measures obtained from claims-based data on Medicare patients only. The commenters supported MedPAC's and other stakeholder's assertions that CDC NHSN chart-abstracted measures in Domain 2 are more reliable and actionable than the claims-based measures in Domain 1.

Response: We agree that an increase in the Domain 2 weight is warranted, given that the number of measures is increasing to include addition of the CDC NHSN Surgical Site Infection (SSI) measure for FY 2016 and the addition of the CDC NHSN *Methicillin-Resistant Staphylococcus aureus* (MRSA) Bacteremia and *C. difficile* measures for FY 2017. We agree that both patient safety events and infections are important components of the HAC Reduction Program. We refer readers to the FY 2014 IPPS/LTCH PPS proposed rule (79 FR 28143 through 29144) for additional information for assigning a higher weight to Domain 2.

Comment: Some commenters objected to the proposed reduction of the weight of Domain 1 to 15 percent in FY 2017. The commenters believed that this approach promotes an overly narrow definition of HACs that places too much emphasis on infections alone. The commenters asserted that, while infections are important patient outcomes, patients are exposed to risks from many of the outcomes in the PSI–90 Composite, such as pressure ulcers, postoperative hemorrhage, or accidental puncture/laceration. The commenters suggested that CMS take a more balanced approach to weighting the existing domains in order to place a high bar for hospitals to avoid preventable infections and harmful complications.

Response: We acknowledge the commenters' concerns. We maintain that the AHRQ PSI–90 measure plays a vital role in patient safety and it continues to comprise an integral part of the HAC Reduction Program with a weight of 15 percent of the Total HAC Score.

Comment: Commenters expressed concerns over the pace of the change in relative weightings and encouraged CMS to use the same domain weighting in both FY 2016 and FY 2017. The commenters stated that changes to the weighing of measurement domains in FY 2017, for which the performance period is already underway, should not be made.

Response: We acknowledge the commenters' concerns. We note that the proposed change in relative weightings, for the FY 2017 program, was based on recommendations from MedPAC and other stakeholders that believe the CDC NHSN chart-abstracted measures in Domain 2 are more reliable and actionable than claims-based measures. We also note that the relative weightings were proposed to be adjusted to account for the additions of the CDC NHSN *Methicillin-Resistant Staphylococcus aureus* (MRSA) Bacteremia and *C. difficile* measures for FY 2017 in Domain 2.

Comment: Commenters expressed apprehension about modifying the relative weighting of the domains before hospital systems have fully understood the effects of the transition from the ICD–9 coding system to the ICD–10 coding system.

Response: We are aware of stakeholder concerns about the potential impacts to hospital performance on quality measures when the ICD–10 coding system is implemented on October 1, 2015, as well as their calls for more extensive testing to understand the impacts before any payments or penalties are implicated. As part of ICD–10 transition planning that has taken place over the past several years, we have performed testing and analyses across the agency with respect to system readiness and claims payments, in addition to extensive education and outreach to providers, vendors, and other payers. CMS' systems for quality programs have been tested and will continue to be tested as ICD–10 data are submitted in order to ensure the accuracy of measure calculations and to monitor and assess the translation of measure specifications to ICD–10, potential coding variation, and impacts on measure performance and payment incentive programs. We will continue to work with stakeholders during the ICD–10 transition to monitor and assess impacts and to address any potential issues that may occur.

Comment: Commenters expressed concerns that the change to the relative weightings may have a disproportionate impact on States that mandate reporting of infections by hospitals and other providers through NHSN. The commenters suggested that CMS undertake a State-by-State review of reporting to determine if there may be a correlation between State-mandated reporting requirements and higher infection rates reported by hospitals and to consider those findings for future program improvements.

Response: We appreciate commenters' concern that the relative weightings may have an impact on states that mandate reporting. However, hospitals can voluntarily report to NHSN, and are highly encouraged to do so, because their HAC scores are dependent on it. We will take the commenters' feedback into future consideration as we strive to improve the HAC Reduction Program.

After consideration of the public comments we received, we are finalizing the Domain 1 and 2 weightings for FY 2017 as proposed.

6. Measure Refinements for the FY 2018 HAC Reduction Program

a. Inclusion of Select Ward (Non-Intensive Care Unit (ICU)) Locations in Certain CDC NHSN Measures Beginning in the FY 2018 Program Year

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24512 through 24513), we proposed measure refinements to the CDC NHSN CLABSI and CAUTI measures that were previously adopted for the HAC Reduction Program to include select ward (non-ICU) locations beginning in the FY 2018 program. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50719), we adopted the CLABSI and CAUTI measures inclusive of pediatric and adult patients in ICUs for the HAC Reduction Program beginning with FY 2015. We noted at that time that the Hospital IQR Program finalized data collection for these measures for adult and pediatric patients in medical, surgical, and medical/surgical wards (also referred to as select ward locations), in addition to ICU locations, effective beginning January 1, 2015, and that we would propose the additional locations for the HAC Reduction Program in the future.

The refined CAUTI and CLABSI measures that include select ward locations in addition to ICU locations

were endorsed by the NQF in 2012. The MAP 2015 final recommendations indicated that the CLABSI and CAUTI measures with ICU and select ward locations be included in the HAC Reduction Program.[110] We note that during the MAP Hospital Workgroup meeting (December 9–10, 2014) and the MAP Coordinating Committee meeting (January 26–27, 2015), some members discussed the benefit of reporting the modified measures publicly before including them in a payment program in order to allow providers and CMS to gain experience with the modified measures. Other members expressed concern that this could delay implementation of an improved measure.[111] The MAP supported the use of the refined measures without stipulating prior public reporting as a condition of support. However, we acknowledge the importance of this consideration and took it into account when considering the timing of implementing the expanded measure in the HAC Reduction Program.

As described in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24512), we considered a number of options for when to begin using the refined measures in the HAC Reduction Program. The CDC NHSN measure data used in the HAC Reduction Program are obtained from data that hospitals report as part of their participation in the Hospital IQR Program. Therefore, due to the timing of the Hospital IQR Program including select ward locations (beginning January 1, 2015), the FY 2017 HAC Reduction Program, using the applicable period of CYs 2014 and 2015 for the CDC NHSN measures, is the first time data from select ward locations could be included in the program. However, using select ward location data in the FY 2017 program would result in hospitals with ICU locations having the opportunity to contribute 2 years of data, while hospitals without ICU locations would have the opportunity to contribute 1 year of data for measure result calculation. We believe this systematically unequal distribution of data could introduce bias in the program and should be avoided. If the introduction of select ward location data for the CLABSI and CAUTI measures is delayed until the FY 2018 HAC Reduction Program (applicable period would likely be CYs 2015 and 2016), all hospitals, regardless of whether or not they have ICUs, would have the opportunity to contribute 2 years of data for measure result calculations.

In addition, delaying implementation until FY 2018 would allow CMS and providers to gain some experience with the impact that the inclusion of these data would have on a hospital's HAC Reduction Program scores. We also considered the possibility of further delaying implementation of the refined measures until the FY 2019 program (applicable period would likely be CYs 2016 and 2017) in order to not include the first year of reporting (CY 2015) in a payment program measure calculation.

After considering these three options, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24512), we proposed to include data from pediatric and adult medical ward, surgical ward, and medical/surgical ward locations in addition to data from adult and pediatric ICU locations for the CDC NHSN CLABSI and CAUTI measures beginning with the FY 2018 HAC Reduction Program. This option balances our belief that the refinement of the CLABSI and CAUTI measures to include select ward locations results in an improved measure that more accurately captures hospital-wide performance regarding these HACs with the need to provide hospitals with the opportunity to submit data for the full period of performance and the desire to gain experience with the refined measures before incorporating them into the HAC Reduction Program. We also believe this measure refinement will allow hospitals that do not have ICU locations to use the tools and resources of the NHSN for quality improvement and public reporting efforts (78 FR 50787).

We invited public comment on our proposal.

Comment: Many commenters supported the proposed measure refinements to include select ward (non-ICU) locations for FY 2018. The commenters stated that the CDC NHSN CLABSI and CAUTI measures are important targets for dedicated surveillance and prevention efforts outside the ICU setting and their inclusion in the program represents a more robust reflection of overall organizational performance. The commenters noted that this proposed change appropriately recognizes the importance of controlling hospital-acquired infections outside of the ICU. Some commenters stated that the proposal would allow hospitals without ICU locations to have a greater opportunity to participate in public reporting and quality improvement. The commenters suggested that CMS, in collaboration with CDC, determine how the standardized infection ratio (SIR) for CAUTI and CLABSI for these two location types will be calculated and displayed, noting that the SIR tends to vary significantly between ICU and select ward locations.

Response: We appreciate the commenters' support. We will consider the recommendation regarding public reporting of hospital SIRs for the future.

Comment: Commenters commended CMS for the thorough assessment undertaken to determine the most appropriate time to implement the CDC NHSN CAUTI and CLABSI measures. One commenter noted that there are significant volumes of incident rates of CLASBI and CAUTI that occur in non-ICU locations. One commenter suggested, in the interim, that CMS provide selected ward (non-ICU) locations with the mechanisms to begin voluntary data collection related to the measures for purposes of calculating performance standards. This commenter noted that these measures are an important tool in measuring efficiency within hospitals in order to reduce costly hospital-acquired infections that can have detrimental effects on the patients who develop them.

Response: We appreciate the commenters' support. The intent of the HAC Reduction Program is to reduce the number of hospital-acquired infections in all areas of the hospital. We believe that including non-ICU ward locations allows us to work toward achieving that aim.

Comment: Many commenters suggested that CMS consider delaying the inclusion of select ward (non-ICU) locations until FY 2019. The commenters suggested CY 2017 to serve as the first performance period, to align with the Hospital VBP Program. The commenters suggested that CMS be consistent in its reporting and payment policies, especially given the overlap of measures between the pay-for-performance programs. Some commenters expressed concerns that clinical laboratories will need training to implement the proposed changes, noting that hospitals would need at least part of 2015 to use as a learning period to implement any finalized infection agent changes.

Commenters suggested that CMS refrain from using CY 2015 as part of the performance period for the refined CDC NHSN CAUTI and CLABSI measures. In the alternative, the commenters suggested that CMS utilize CY 2016 as the 1-year performance period if it insisted on incorporating the refined measures in FY 2018, or using a 12-month performance-reporting period. Some commenters suggested that CMS

[110] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78853.*

[111] Ibid.

consider providing additional details about the NHSN locations that are included and excluded.

Response: We appreciate the commenters' concern and suggestions. We note that implementation of the modified CLABSI and CAUTI measures that include expansion outside the ICU were discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50787). We further note that the modified CLABSI and CAUTI measures that include expansion outside the ICU were included on the 2014 Measures Under Consideration list and were discussed and generally supported by the MAP Hospital Workgroup at its December 2014 meeting. We believe that implementation of the expanded measures in FY 2018 will allow more hospitals to have their performance monitored during FY 2018 by including hospitals without ICUs that were previously not included, or small hospitals with ICUs that previously lacked enough data to calculate a standardized infection ratio (SIR).

Allowing FY 2017 to serve as the first program year would permit hospitals with ICU locations to contribute 2 years of data, while hospitals without ICU locations would only have 1 year of data to contribute for measure result calculations. We believe this unequal distribution of data could introduce bias in the program and should be avoided. We note that implementation in FY 2018 would allow all hospitals, regardless of whether or not they have ICUs, to have the opportunity to contribute 2 years of data for measure result calculations. This option balances our belief that the refinement of the CLABSI and CAUTI measures to include select ward locations results in an improved measure that more accurately captures hospital-wide performance.

To address the commenters' specific point to delay implementation to align the HAC Reduction Program with the Hospital VBP Program, we continue to stress that the HAC Reduction Program and the Hospital VBP Program are separate programs with different purposes and policy goals. The HAC Reduction Program incentivizes the improvement of patient safety in hospitals by reducing payments to hospitals for excess HACs, while the Hospital VBP Program is an incentive program that redistributes a portion of the Medicare payments made to hospitals based on their performance on various measures. We also note that the Hospital VBP Program has a specific statutory requirement at section 1886(o)(2)(C)(i) of the Act that measures selected under the program must have had measure data posted on *Hospital Compare* for 1 year prior to the performance period; the HAC Reduction Program has no such analogous requirement.

Comment: One commenter requested to know when the CDC NHSN CAUTI and CLABSI results, reflecting the expanded population, would be reported on *Hospital Compare.*

Response: FY 2018 HAC Reduction Program results will be publicly reported on *Hospital Compare* around December 2017. As previously finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50725), we will publicly report the following on the *Hospital Compare* Web site: (1) Hospital scores with respect to each measure; (2) each hospital's domain specific score; and (3) the hospital's Total HAC Score.

Comment: One Commenter suggested that CMS provide an analysis of the impact of the expansion of the CDC NHSN measures on the program. The commenter noted that this is a relatively recent expansion and additional information regarding its impact should be made available to stakeholders prior to implementation.

Response: We appreciate the commenter's suggestion. We will determine the feasibility of conducting an impact analysis of the CDC NHSN measures on the HAC Reduction Program.

Comment: One commenter expressed concerns that expanding the CDC NHSN CAUTI data collection to non-ICU wards may endanger patients with spinal cord injury/dysfunction (SCI), unless they are excluded from the measure. The commenter noted that, in response to the CDC NHSN CAUTI measure, a number of hospitals and hospital systems have encouraged removal of indwelling catheters, often without recognizing spinal cord injury patients as an at-risk population. The commenter stated that premature catheter removal has resulted in improper and unsafe bladder management in the acute care and subacute care settings.

Response: We appreciate the commenter's suggestion on excluding SCI patients from CAUTI reporting. Patient exclusions are determined by the measure steward, which is the CDC. We are currently using the CAUTI measure as specified by the CDC in the HAC Reduction Program, which includes SCI patients. Questions concerning CDC NHSN measures should be addressed to *NHSN@cdc.gov*.

After consideration of the public comments we received, we are finalizing the inclusion of data from pediatric and adult medical ward, surgical ward, and medical/surgical ward locations, in addition to data from adult and pediatric ICU locations for the CDC NHSN CLABSI and CAUTI measures, beginning in FY 2018, as proposed.

b. Update to CDC NHSN Measures Standard Population Data

In this section, we provide information regarding upcoming changes to the standard population data that are used to calculate the SIR for the CDC NHSN measures. These changes are occurring as part of routine measure maintenance.

The CDC NHSN measures are used to monitor hospital performance on prevention of healthcare-associated infections (HAIs). For each NHSN measure, CDC calculates the SIR, which compares a hospital's observed number of HAIs to the number of infections predicted for the hospital, adjusting for several risk factors.[112] The predicted number of infections is determined using patient care location characteristics (for example, the number of central line days) and infection rates that occurred among a standard population during a specified time period (sometimes referred to by CDC as ''national baseline'' but referred to here as ''standard population data''). For example, CDC currently uses data collected in CY 2009 for the CAUTI measure to determine the standard population data.[113] For more information about the method by which NHSN measures are calculated, we refer readers to QualityNet's Web page on HAI measures, which may be found at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021*.

As part of routine measure maintenance, CDC will be updating the standard population data to ensure the NHSN measures' number of predicted infections reflects the current state of HAIs in the United States.[114] Beginning January 1, 2015, CDC started collecting data to use in updating the standard population data for HAI measures. (The CY 2015 standard population data for HAI measures will hereinafter be referred to as ''new standard population data.'') Measure results using infections reported in CY 2016 will reflect the use of the new standard population data. It is anticipated that the new standard population data will affect the HAC

[112] Available at: *http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf*.

[113] Available at: *http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf*; and *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html*.

[114] Available at: *http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf*.

Reduction Program beginning in FY 2018 when the applicable period for the CDC NHSN measures included in the program is likely to include CY 2015 and CY 2016.

Comment: Many commenters supported the adoption of updated standard population data in the calculation of SIRs for the CDC NHSN measures to ensure that the predicted number of infections used in the measures are based on the most recent data.

Response: We appreciate the commenters' recognition of the importance to update the baselines used to calculate HAI performance to ensure use of the most recent data.

Comment: Many commenters objected to how CMS will incorporate the updated standard population data. The commenters noted that only measure results reported in CY 2016 would utilize the new standard population data, resulting in the FY 2018 penalty determinations being based upon data from different standard populations for the 2 reporting years. The commenters suggested that, for reliability purposes, CMS explore other options to implement the standard population data change to ensure that 2 years of performance data are calculated under the same methodology. The commenters suggested that the incorporation of the updated standard population data be accomplished in a way that allows hospitals ample time to be able to review, understand, and explain the changes in performance that may occur before the changes affect payment. The commenters also suggested that CMS engage in further conversations with CDC and hospital stakeholders to evaluate different approaches for implementation prior to a final decision.

Response: We acknowledge the commenters' concerns and appreciate their suggestions. To provide clarification regarding use of the updated standard population data, the FY 2018 program will use SIRs for CY 2015 and CY 2016 that will be calculated using the new standard population data that are based on CY 2015 data reported to NHSN. There will not be two different standard populations used to determine FY 2018 measure results or scores; only the new standard population will be used. The CDC will use CY 2015 data to obtain the national rate and then will use this new national rate to calculate the SIRs for CY 2015 and CY 2016 in connection with the FY 2018 HAC Reduction Program.

Comment: Commenters expressed concerns that using the rebased and expanded measures in FY 2018 would result in the HAC Reduction Program implementing these measures a full year earlier than in the Hospital VBP Program. The commenters noted that there is value in implementing the rebased measures in FY 2019 for both programs. The commenters noted that standardizing CDC data collection for these two programs leads to less confusion during data reporting. The commenters suggested delaying the implementation of the newly rebased and expanded measures until FY 2019.

Response: We appreciate commenters' concern. CDC's new CAUTI definition was developed by a subject-matter expert working group comprised of CDC and non-CDC participants who systematically assessed each definitional component. The result is a new CAUTI definition that is simplified from previous iterations and allows for less subjectivity while optimizing clinical credibility. An assessment of the impact of the definition change on CAUTI incidence was completed as part of the definition development. In addition, the NHSN application provides a technical infrastructure and built-in controls on data entry that serve as safeguards against the reporting of events that do not meet the new CAUTI definition. For these reasons, CDC is confident that the CAUTI data reported in CY 2015 will be appropriate to use for a new standard population.

To address commenters' concerns about program overlap, we note that the Hospital VBP Program has a specific statutory requirement at section 1886(o)(2)(C)(i) of the Act that measures selected under the program must have had measure data posted on *Hospital Compare* for 1 year prior to the performance period; the HAC Reduction Program has no such analogous requirement. We will continue to look at ways to better align the two programs in the future.

Comment: One commenter suggested that CMS revise the SIR methodology or exclude hospitals with low-volumes that may lack sufficient cases to establish an expected infection calculation. The commenter noted that when the Expected Infection Value is less than one, CMS deems the ratio invalid, and eliminates the Infection Prevention Component (Domain 2) from the overall performance roll-up. The commenter noted that this results in all of the weighting criteria shifting to the patient safety domain (Domain 1).

Response: We appreciate the commenter's suggestions and will take them under advisement as we seek to make our measures more transparent. We conferred with CDC, which indicated that they continuously evaluate the data reported to NHSN and consider the best measures for monitoring and comparative purposes. Currently the SIR is the best measure to allow for risk adjustment and production of a facility-level and/or CCN-level metric that can be used for comparison across similar facility types. This provides the opportunity to most accurately represent a facility's success. CDC continues to review the data and evaluate options for metric development, including situations where facilities have low denominator volume and/or few infections.

7. Maintenance of Technical Specifications for Quality Measures

Technical specifications for AHRQ's PSI–90 Composite measure in Domain 1 can be found at AHRQ's Web site at: *http://qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx*. Technical specifications for the CDC NHSN HAI measures in Domain 2 can be found at CDC's NHSN Web site at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both Web sites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100), we described a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24513), we did not propose any changes to this policy.

8. Extraordinary Circumstance Exception Policy for the HAC Reduction Program Beginning in FY 2016 and for Subsequent Years

a. Background

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28142), we welcomed public comment on whether a potential waiver or exception policy for hospitals located in areas that experience disasters or other extraordinary circumstances should be implemented, and the policy and operational considerations of such an extraordinary circumstance exception policy for the HAC Reduction Program. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50101), we indicated that we received many comments in support of CMS establishing a formal extraordinary circumstance exception policy under the HAC Reduction Program. We also previously indicated that any specific proposals related to the implementation of an extraordinary circumstance exception policy would be proposed through notice-and-comment

rulemaking. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24513 through 24514), we proposed to establish an extraordinary circumstance exception policy for the HAC Reduction Program beginning in FY 2016 and for subsequent years.

In developing this proposed extraordinary circumstance exception policy for the HAC Reduction Program beginning in FY 2016 and for subsequent years, we considered a policy and process similar to that for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended § 412.40(c)(2)) to refer to ''extension or exemption'' instead of the former ''extension or waiver''). We also considered how best to align an extraordinary circumstance exception policy for the HAC Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital VBP Program, to the extent feasible.

We considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's measure results or Total HAC Score for the applicable performance period. By minimizing the data excluded from the program, the proposed policy would enable affected hospitals to continue to participate in the HAC Reduction Program for a given fiscal year if they otherwise continue to meet applicable measure minimum threshold requirements. We believe that this approach could help alleviate the reporting burden for a hospital that is adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the HAC Reduction Program.

b. Requests for an Extraordinary Circumstance Exception

Based upon our prior experience with the Hospital IQR Program and the Hospital VBP Program, we anticipate the need to provide exceptions to only a small number of hospitals affected by a natural disaster or other extraordinary circumstance. During the review of a hospital's request for an extraordinary circumstance exception, we will maintain the general principle that providing high quality of care and ensuring patient safety is of paramount importance. We do not intend to allow a hospital to use this proposed policy and the request process to seek exclusion from the HAC Reduction Program in its entirety for a given fiscal year(s) solely because of experiencing an extraordinary circumstance. Rather, we intend to provide relief for a hospital whose ability to accurately collect quality measure data and/or to report those data in a timely manner has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital. Section 1886(p)(4) of the Act permits the Secretary to determine the ''applicable period'' for HAC data collection, and we believe that the statute allows us to determine that the period not include times when hospitals may encounter extraordinary circumstances.

We proposed that the request process for an extraordinary circumstance exception begin with the submission of an extraordinary circumstance exception request form by a hospital within 90 calendar days of the natural disaster or other extraordinary circumstance. We believe that the 90-calendar day timeframe is an appropriate period of time for a hospital to determine whether to submit an extraordinary circumstance exception request. It is also the same length of time as the current time period allowed under the Hospital VBP Program. Under this proposed policy, a hospital would be able to request a HAC Reduction Program extraordinary circumstance exception at the same time it may request a similar exception under the Hospital IQR Program, the Hospital VBP Program, and the Hospital Readmissions Reduction Program (if an extraordinary circumstance exception policy is adopted for the Hospital Readmissions Reduction Program as described in section IV.E.9. of the preamble of FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24497 through 24498)). The extraordinary circumstance exception request form would be made available on the QualityNet Web site (*https://www.qualitynet.org/*).

The following minimum set of information would be required to submit the request:

- Hospital CCN;
- Hospital name;
- Hospital Chief Executive Officer (CEO) and any other designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address; a post office box address is not acceptable);
- Hospital's reason for requesting an exception, including:

++ CMS program name (for example, the HAC Reduction Program, the Hospital VBP Program, or the Hospital IQR Program);

++ The measure(s) and submission quarters affected by the extraordinary circumstance that the hospital is seeking an exception for should be accompanied with the specific reasons why the exception is being sought; and

++ How the extraordinary circumstance negatively impacted performance on the measure(s) for which an exception is being sought;

- Evidence of the impact of the extraordinary circumstances, including but not limited to, photographs, newspaper articles, and other media articles; and
- The request form must be signed by the hospital's CEO or designated non-CEO contact and submitted to CMS.

The same set of information is currently required under the Hospital IQR Program and the Hospital VBP Program on the request form from a hospital seeking an extraordinary circumstance exception with respect to these programs. The specific list of required information would be subject to change from time to time at the discretion of CMS.

Following receipt of the request form, CMS would: (1) Provide a written acknowledgement of receipt of the request using the contact information provided in the request form to the CEO and any additional designated hospital personnel; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of the CMS decision. Under the proposed policy, we would review each request for an extraordinary circumstance exception on a case-by-case basis at CMS' discretion. To the extent feasible, we also would review such a request in conjunction with any similar requests made under other IPPS quality reporting and payment programs, such as the Hospital IQR Program and the Hospital VBP Program.

The proposed policy would not preclude CMS from granting extraordinary circumstance exceptions to hospitals that do not request them if we determine at our discretion that a disaster or other extraordinary circumstance has affected an entire region or locale. If CMS makes such a determination to grant an extraordinary circumstance exception to hospitals in an affected region or locale, we would convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited, to issuing memos, emails, and

notices on the QualityNet Web site at: *https://www.qualitynet.org/*. This provision also would align with the Hospital IQR Program's extraordinary circumstances extension or exemption policy, as set forth in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651).

We invited public comment on this proposal.

Comment: Many commenters supported the proposal to establish an extraordinary circumstance exception policy. The commenters appreciated that CMS previously implemented similar policies for other quality reporting programs and agreed that policies should be consistent across programs. The commenters appreciated that penalties will not be imposed for failure to meet goals related to natural or manmade disasters, overwhelming epidemics, or catastrophic failures of infrastructure. The commenters recommended that CMS develop a single request form, encompassing all quality reporting programs from which a hospital might request an exception. The commenters noted that the request form could list all of the various quality reporting programs and require a hospital to check off the programs for which it has encountered difficulty collecting data.

Response: We appreciate the commenters' support for the adoption of an extraordinary circumstance exception policy for the HAC Reduction Program. We also appreciate the recommendations from the commenters and will take into consideration these recommendations as we implement operational processes.

Comment: One commenter suggested that CMS adopt an extraordinary circumstance exception that allows for at least a 1-year exemption from the HAC Reduction Program. The commenter stated that an exception policy of at least 1 year would allow hospitals to focus on and address their immediate needs during a time of crisis and to recover from physical damage and data lags. The commenter noted that hospitals struggling with an extraordinary circumstance may face a truncated reporting period and may have a low volume of data to report, resulting in inconsistent and unreliable outcomes.

Response: We appreciate the commenter's suggestion. Each request for an extraordinary circumstance exception will be reviewed on a case-by-case basis. Determinations will be based on the information a hospital submits in connection with the reason for the request, such as: The measure(s) and submission quarters affected by the extraordinary circumstance; how the extraordinary circumstance negatively impacted performance on the measure(s); and evidence of the impact.

Comment: One commenter suggested that CMS consider a range of extenuating circumstances that could adversely affect a hospital's ability to submit data in a timely fashion. The commenter also suggested that CMS allow an appeals process to govern extraordinary circumstance exception decisions.

Response: We appreciate the commenter's recommendations. As we discussed in the proposed rule (80 FR 24497), based on our experience with the Hospital Value-Based Purchasing Program and the Hospital Inpatient Quality Reporting Program, we anticipate a need to provide exemptions only to a small number of hospitals where the ability to accurately or timely submits claims has been directly impacted. We will continue to monitor extraordinary circumstance exception requests to ensure that the process we are adopting in this final rule supports the goals of the HAC Reduction Program. However, we do not intend to modify the criteria for an extraordinary circumstance exception at this time. We do not anticipate a need to establish an appeals process for extraordinary circumstance exception determinations.

Comment: One commenter asked if an exception for FY 2015 will be granted if an extraordinary circumstance occurred prior to implementation of the final rule.

Response: We are finalizing the extraordinary circumstance exception policy beginning in FY 2016, as was proposed. Therefore, exceptions may only be granted for circumstances occurring on or after October 1, 2015.

After consideration of the public comments we received, we are finalizing the extraordinary circumstance exception policy as proposed.

H. Simplified Cost Allocation Methodology for Hospitals (§ 412.302)

1. Background

The Medicare hospital cost report employs a cost-finding methodology to allocate direct and indirect costs using statistics appropriate to each department within a hospital. The costs of nonrevenue-producing cost centers (general service or overhead cost centers) are allocated to each other and to the revenue-producing cost centers using statistical bases and related statistics that measure the amount of service furnished by each cost center to the other cost centers (42 CFR 413.24(b) and (d)). In this regard, cost-finding is the process of recasting the data derived from the accounts ordinarily kept by a hospital to ascertain costs of the various types of services furnished (42 CFR 413.24(b)(1)).

In the FY 1997 IPPS final rule (61 FR 46214 through 46215), CMS implemented the simplified cost allocation methodology at 42 CFR 412.302(d)(4) for hospitals as an alternative to the standard cost-finding methodology. The simplified cost allocation methodology reduces the number of statistical bases that a hospital must maintain. Under the simplified cost allocation methodology, a hospital must use a prescribed list of statistical bases, without deviation, as set forth in the Provider Reimbursement Manual (PRM), Part II (CMS Pub. 15–2), Chapter 40, Section 4020, Form CMS–2552. The simplified cost allocation methodology was devised in response to concerns expressed by the hospital industry over 20 years ago regarding the high costs of the recordkeeping required under the cost reporting rules. Since implementation of the simplified cost allocation methodology, there have been advances in technology of recordkeeping for hospitals, resulting in less arduous and costly recordkeeping. It was expected that, although use of the simplified cost allocation methodology by hospitals would result in reduced recordkeeping costs, it also would likely result in reduced Medicare payments to hospitals.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we created standard cost centers for Magnetic Resonance Imaging (MRI) and computed tomography (CT) scans, and required that hospitals report the costs and charges for these services under new cost centers on the Medicare cost report Form CMS–2552–10. The new standard cost centers for MRIs and CT scans were effective for cost reporting periods beginning on or after May 1, 2010.

Beginning in FY 2014, we started to calculate the MS–DRG relative weights using 19 CCRs, including distinct CCRs for MRIs and CT scans. In addition, beginning in the CY 2014 OPPS, we started to calculate the OPPS relative payment weights using distinct CCRs for MRIs and CT scans. Some stakeholders expressed concern that CMS was not appropriately determining the cost of advanced imaging for inpatient and outpatient hospital services because, when the costs of hospitals that use the simplified cost allocation methodology are included in cost determinations, less precise CCRs are generated. This is because the simplified cost allocation methodology requires a hospital to use

square footage instead of dollar value for capital-related moveable equipment. In response to public comments on the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27486) and the CY 2014 OPPS/ASC proposed rule (78 FR 43547), in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50521 through 50523) and in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74843 through 74847), we encouraged hospitals to use the statistical basis of ''dollar value'' for the costs of capital-related movable equipment, especially for costly MRI and CT imaging equipment, to support a more precise cost allocation and, therefore, more precise CCRs. However, a hospital that obtained approval from their MAC, under Section 2313 of the Provider Reimbursement Manual (PRM), Part I (CMS Pub. 15–1), to use the simplified cost allocation methodology set forth in Section 4020 of CMS Pub. 15–2 was restricted by the required statistical basis of ''square footage'' for costs of capital-related movable equipment. We recommended that hospitals use the statistical basis of the dollar value or use the ''Direct Assignment of General Service Cost'' method by requesting MAC approval in accordance with Section 2307 of CMS Pub. 15–1.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24514 through 24515), we proposed to eliminate the simplified cost allocation methodology because, as discussed above, the allocation of the costs of capital-related movable equipment using the required basis (square footage) under the simplified cost allocation methodology, instead of the recommended basis (dollar value) yields less precise calculated CCRs. We stated in the proposed rule that, currently, less than 1 percent of hospitals have elected to use the simplified cost allocation methodology. Based on FY 2013 HCRIS data, we stated that only 9 of 1,269 CAHs and 23 of 4,389 hospitals other than CAHs used the simplified cost allocation methodology. Furthermore, we stated that we believe that advances in technology have reduced the cost of recordkeeping, allowing hospitals to maintain accurate statistical data and affording them the flexibility to change to a more precise allocation methodology.

2. Proposed Regulatory Change

The regulations applicable to the election of the simplified cost allocation methodology are located in 42 CFR 412.302. For the reasons set forth in section IV.H.1. of the preamble of the FY 2016 IPPS/LTCH proposed rule (80 FR 24514 through 24515), we proposed to amend § 412.302 by revising paragraph (d)(4) to eliminate a hospital's ability to elect the simplified cost allocation methodology under the terms and conditions provided in the instructions for CMS Form 2552 for cost reporting periods beginning on or after October 1, 2015.

3. Summary of Public Comments, Our Responses, and Final Changes

We set forth below summaries of the public comments that we received and our responses to those public comments.

Comment: Commenters questioned the accuracy of CMS' data as cited in the proposed rule with regard to the number of hospitals that use the simplified cost allocation methodology. The commenters stated that if the data included hospitals that answered ''Yes'' to the question on Worksheet S–2, line 149 of the Medicare cost report, ''Was there a change to the simplified cost-finding method?'', the CMS' data were incorrect. Commenters pointed out that hospitals that answered ''Yes'' to this question are only those hospitals that changed their cost-finding method to the simplified cost allocation methodology. A few commenters suggested that the number of hospitals using the simplified cost allocation methodology was closer to 2,000 if the number captures those hospitals that used the square footage statistic for both the ''building and fixtures'' and ''movable equipment'' cost centers.

Response: We appreciate the commenters' concerns regarding the accuracy of the data cited in the proposed rule regarding the number of hospitals that currently use the simplified cost allocation methodology. In response to the commenters, we reassessed the data for the 5,658 hospitals reported in the FY 2013 HCRIS, based on the statistical basis reported for each general services cost center, and found that there are less than 100 hospitals using the simplified cost allocation methodology. We agree with the commenters' conclusions that capturing hospitals who answered ''Yes'' to the question on Worksheet S–2, line 149 of the Medicare cost report will not represent the number of hospitals who use the simplified cost allocation methodology. We believe the commenters' concerns regarding the accuracy of the data result from a misconception of what it means to use the simplified cost allocation methodology. The simplified cost allocation methodology is only indicated by hospitals that use the *entire list* of the statistical bases as required by Section 4020 of CMS Pub. 15–2. We based the data cited in the proposed rule on the FY 2013 HCRIS data and selected only those hospitals that used the entire list of statistical bases as required by and set forth in Section 4020 of CMS Pub. 15–2. Hospitals that used one or more, but not all, of the statistical bases are not using the simplified cost allocation methodology and were not included in our data analysis in the proposed rule because the simplified cost allocation methodology is only denoted by hospitals that use each and every statistical basis on the prescribed list in Section 4020 of CMS Pub. 15–2. For example, hospitals that use square footage as a statistical basis for both the ''building and fixtures'' and ''movable equipment'' cost centers, but deviate from any one of the other statistical bases required from the list of 19 cost centers under the simplified cost allocation methodology, are not using the simplified cost allocation methodology.

Using the FY 2013 HCRIS data, we applied filters using the 19 statistical bases required by the simplified cost allocation methodology and determined that less than 100 hospitals used the simplified cost allocation methodology. We began with a total hospital population of 5,658 from the FY 2013 HCRIS. First, we applied a filter to the 5,658 hospitals for the ''buildings and fixtures'' and ''movable equipment'' cost centers using square footage as the statistical basis for the simplified cost allocation methodology and determined that 3,337 hospitals used this basis. In so doing, we were able to eliminate 2,321 hospitals that were not using the simplified cost allocation methodology's basis of square footage for these cost centers. We then applied a second filter to the 3,337 hospitals for the ''laundry and linen'' cost center using patient days as the statistical basis for the simplified cost allocation methodology and determined that 1,008 hospitals used patient days. After applying the second filter, we were able to eliminate an additional 2,329 hospitals that may have used square footage but were not using the simplified cost allocation methodology's basis of patient days for this cost center; in most cases, hospitals used pounds of laundry or an alternative basis not within the simplified cost allocation methodology. We next applied a third filter to the resulting 1,008 hospitals for the ''dietary'' cost center using patient days as the statistical basis for the simplified cost allocation methodology and determined that 687 hospitals used patient days. After applying the third

filter, we were able to eliminate an additional 321 hospitals that were not using the simplified cost allocation methodology's basis of patient days for this cost center. With the resulting 687 hospitals, we next applied a fourth filter for the ''nursing administration'' cost center using nursing salaries as the statistical basis for the simplified cost allocation methodology and determined that 523 hospitals used nursing salaries. In this manner, we continued filtering through the simplified cost allocation methodology's remaining costs centers and corresponding statistical bases and ended with a result of less than 100 hospitals using the simplified cost allocation methodology.

In our original data analysis set forth in the proposed rule, we excluded hospitals with cost centers that were listed in the HCRIS report as blank because we assumed that if a cost center was blank, a hospital was not using the simplified cost allocation methodology. However, upon revisiting the data following the receipt of public comments, we determined that if a cost center was blank, it did not necessarily mean the hospital was not using the simplified cost allocation methodology. In this regard, we broadened the filters to include hospitals with the blank cost centers which broadened the population. Within this larger population, we concluded that there were more hospitals using the simplified cost allocation methodology than originally cited in the proposed rule. Although this second data analysis was more conservative and included a larger population, we still found that less than 100 hospitals are using the simplified cost allocation methodology.

Comment: Some commenters stated that CMS should explore alternatives to eliminating the simplified cost allocation methodology rather than disrupting the cost reporting practices of a large number of hospitals that do not use ''dollar value'' to allocate capital-related moveable equipment.

Response: We appreciate the commenters' concerns and believe that it is important to minimize disruption of hospital cost reporting practices, while at the same time allowing hospitals to use a more precise statistical allocation basis of dollar value. Therefore, in response to comments, in this final rule, rather than eliminating the simplified cost allocation methodology as we proposed, we are modifying the simplified cost allocation methodology to permit the use of either dollar value or square footage as the statistical basis for capital-related moveable equipment. With this modification, we believe there will be no disruption of cost reporting practices for hospitals, regardless of whether or not they use the simplified cost allocation methodology. While hospitals currently using the standard cost-finding method of allocation may also use an approved alternative statistical basis of square footage for capital-related moveable equipment and can request approval to change back to the recommended and more precise statistical allocation basis of dollar value, hospitals using the simplified cost allocation methodology are not afforded this same flexibility to change to dollar value as a statistical basis for capital-related moveable equipment. Currently, under the simplified cost allocation methodology, there can be no deviation from the prescribed statistical bases for any of the cost centers as set forth in the PRM (CMS Pub. 15–2, Chapter 40, Section 4020, Form CMS–2552–10). Under our modified policy, hospitals that use the simplified cost allocation methodology (that is, hospitals that use each and every statistical basis within the list of cost centers under the simplified cost allocation methodology) may continue their use of these statistical bases, with the added flexibility to request approval to use the dollar value statistical basis for capital-related moveable equipment. In this regard, hospitals using the simplified cost allocation methodology will no longer be required to use the square footage statistical basis for capital-related moveable equipment but will be provided greater flexibility to request approval to use the statistical basis of dollar value which may be better suited to their cost allocation needs. We note that hospitals currently using one or more, but not all, of the statistical bases under the simplified cost allocation methodology are not considered to be using the simplified cost allocation methodology. Rather, they are considered to be using the standard cost-finding methodology with approved alternative statistical bases. These hospitals may continue to use these previously approved statistical bases. As discussed above and in the proposed rule, we believe that advances in recordkeeping information technology since the simplified cost allocation methodology was devised almost 20 years ago have afforded hospitals the ability to more accurately track data and costs with relative ease and to more quickly recall such data than in the past. Thus, we believe that hospitals should use the cost allocation methodology that results in the most precise cost allocation.

Comment: A few commenters suggested that CMS provide data to support its belief that using dollar value as a statistic for capital-related moveable equipment will result in more precise CCRs and will outweigh the additional reporting burden to hospitals.

Response: We appreciate the commenters' concerns surrounding the perceived burden to hospitals and the use of dollar value as a statistic for capital-related moveable equipment to support more precise CCRs. As noted in the proposed rule, beginning in FY 2014, we started to calculate the MS–DRG relative weights using 19 CCRs, including distinct CCRs for MRIs and CT scans. In addition, beginning in the CY 2014 OPPS, we started to calculate the OPPS relative payment weights using distinct CCRs for MRIs and CT scans. In public comments, some stakeholders, including the hospital industry, expressed concern that CMS was not appropriately determining the cost of advanced imaging for inpatient and outpatient hospital services because, when the costs of hospitals that use the simplified cost allocation methodology, or square footage as a statistical basis for capital-related moveable equipment, are included in cost determinations, less precise CCRs are generated. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50077), we notified hospitals of the need and importance of properly reporting the capital costs of moveable equipment on the Medicare cost report and recommended that hospitals use the statistical allocation method of ''dollar value'' for costs on Worksheet A, Column 2 for Capital-Related Costs—Moveable Equipment, or by requesting contractor approval in accordance with Section 2307 of CMS Pub. 15–1 to use the ''direct assignment'' allocation method. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53283), we reiterated this recommendation so that when distinct CCRs for MRI and CT scan would be proposed, the CCRs would fairly and accurately represent the cost of these costly imaging equipment. We encouraged hospitals to use the statistical basis of ''dollar value'' for the costs of capital-related movable equipment, especially for costly MRI and CT imaging equipment.

Dollar value is the statistical basis that uses the actual cost of the asset being depreciated and more accurately allocates costs among the cost centers using those assets. In the CY 2014 OPPS/ASC final rule with comment period, we indicated that commenters had expressed concern that the use of square footage as the statistical basis of allocation ''results in CCRs that lack face validity'' (78 FR 74843 through 74847). It has been CMS' longstanding

policy that hospitals use dollar value as the recommended default statistical basis for capital-related moveable equipment. As discussed above, currently under the simplified cost allocation methodology, hospitals are required to use square footage as the statistical basis for capital-related moveable equipment. Thus, we are finalizing a policy that affords hospitals using the simplified cost allocation methodology the flexibility to use either square footage or dollar value as a statistical basis for capital-related moveable equipment. However, we encourage all hospitals, regardless of their cost-finding methodology, to use dollar value as a statistical basis for the capital-related moveable equipment cost center because we believe it results in more precise CCRs.

Comment: Some commenters believed that, despite advances in technology and recordkeeping for hospitals, the elimination of the simplified cost allocation methodology would create a significant administrative burden.

Response: We appreciate the commenters' concern regarding the additional burden to hospitals with the elimination of the simplified cost allocation methodology. As discussed earlier, we are not finalizing our proposal to eliminate the simplified cost allocation methodology. Instead, we are modifying the simplified cost allocation methodology to give hospitals greater flexibility to request approval from their MACs to use the statistical basis of dollar value for capital-related moveable equipment. In this regard, we do not foresee any burden to any hospitals. Instead, we believe greater flexibility is being afforded.

In summary, after consideration of the public comments we received, we are not finalizing our proposal to eliminate the simplified cost allocation methodology. Instead, we are modifying the simplified cost allocation methodology set forth at CMS Pub. 15–2, Chapter 40, Section 4020, to provide additional flexibility to hospitals that use the simplified cost allocation methodology by allowing them to obtain approval from their MACs to use an alternative statistical basis of dollar value for capital-related moveable equipment. In this regard, hospitals using the simplified cost allocation methodology will no longer be restricted to using square footage as a statistical basis for capital-related moveable equipment. Instead, hospitals using the simplified cost allocation methodology may obtain MAC approval in accordance with the instructions set forth in Section 2313 of CMS Pub. 15–1 to use either square footage or dollar value as the statistical basis for capital-related moveable equipment. However, we encourage all hospitals, regardless of their cost-finding methodology, to use dollar value as a statistical basis for the capital-related moveable equipment cost center because we believe it results in more precise CCRs.

Hospitals that are not currently using the simplified cost allocation methodology but desire to do so will need to obtain approval from their MACs, consistent with our current policy set forth at Section 2313 of CMS Pub. 15–1. MACs will approve new requests to use the simplified cost allocation methodology if the hospital demonstrates that the maintenance of the new statistics is less costly and the use does not result in inappropriately shifting costs.

Hospitals that are not using the simplified cost allocation methodology but are using one or more, but not all, of the statistical bases from the cost center list under the simplified cost allocation methodology in Section 4020, Chapter 40 of CMS Pub. 15–2 and have been permitted to do so by their MACs, will continue to be permitted to request such usage from their MACs.

I. Rural Community Hospital Demonstration Program

1. 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 program and converted to CAH status. This left nine hospitals participating at that time. In 2008, we announced a solicitation for up to six additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These four additional hospitals began under the demonstration payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the demonstration program during CYs 2009 and 2010. (Three of these hospitals indicated that they would be paid more for Medicare inpatient hospital services under the rebasing option allowed under the SCH methodology provided for under section 122 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). One hospital restructured to become a CAH, and one hospital closed.) In CY 2011, one hospital that was among the original set of hospitals that participated in the demonstration withdrew from the demonstration. These actions left seven of the originally participating hospitals (that is, 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 is 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. Furthermore, in the case of a rural community hospital that is participating in the demonstration program as of the last day of the initial 5-year period, the Affordable Care Act requires the Secretary to provide for the continued participation of such rural hospital in the demonstration program during the 5-year extension period, unless the hospital makes an election to discontinue participation.

In addition, the Affordable Care Act provides that, during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary to 20. Furthermore, the Secretary is required to use the same criteria and data that the Secretary used to determine the States for the initial 5-year period. The Affordable Care Act also allows 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). Applications were due on October 14, 2010. The 20 States with the lowest population density that were eligible for the demonstration program are: 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). We approved 19 new hospitals for participation in the demonstration program. We determined that each of these new hospitals would begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011.

Three of these 19 hospitals declined participation prior to the start of the cost reporting periods for which they would have begun the demonstration. 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 among the set selected in 2011 withdrew from the demonstration, similarly citing a relative financial advantage to returning to the customary SCH payment methodology, which left 22 hospitals participating in the demonstration.

In addition, section 410A(c)(2) of Public Law 108–173 required that, in conducting the demonstration program under this section, the Secretary must 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 in 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, makes it extremely unlikely that this demonstration program could be viable under the usual form of budget neutrality.

Specifically, cost-based payments to participating small rural hospitals are likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration program is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these same hospitals.

In the past 11 IPPS final rules, spanning the period for which the demonstration program has been implemented, we have 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. As we discussed in the FYs 2005 through 2015 IPPS 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, and 79 FR 50141, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

In general terms, in each of these previous years, we used available cost reports for the participating hospitals to derive an estimate of the additional costs attributable for the demonstration. Prior to FY 2013, we used finalized, or settled, cost reports, as available, and ''as submitted'' cost reports for hospitals for which finalized cost reports were not available. Annual market basket percentage increase amounts provided by the CMS Office of the Actuary reflecting the growth in the prices of inputs for inpatient hospitals were applied to these cost amounts. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53452), we used ''as submitted'' cost reports (for cost reporting periods ending in CY 2010) for each hospital participating in the demonstration in estimating the costs of the demonstration. In addition, in FY 2013, we incorporated different update factors (the market basket percentage increase and the applicable percentage increase, as applicable, to several years of data as opposed to solely using the market basket percentage increase) for the calculation of the budget neutrality offset amount. Finally, in each of the previous years, an annual update factor provided by the CMS Office of the Actuary reflecting growth in the volume of inpatient operating services also was applied. For the budget neutrality calculations in the IPPS final rules for FYs 2005 through 2011, the annual volume adjustment applied was 2 percent; for the IPPS final rules for FYs 2012, 2013, 2014, and 2015, it was 3 percent. For a detailed discussion of our budget neutrality offset calculations, we refer readers to the IPPS final rule applicable to the fiscal year involved.

In general, for FYs 2005 through 2009, we based the budget neutrality offset estimate on the estimated cost of the demonstration in an earlier given year. For these periods, we derived that estimated cost by subtracting the estimated amount that would otherwise be paid without the demonstration in an earlier given year from the estimated amount for the same year that would be paid under the demonstration under the reasonable cost-based methodology authorized by section 410A of Public Law 108–173. The reasonable cost-based methodology authorized by section 410A of Public Law 108–173, as amended, is hereafter referred to as the ''reasonable cost methodology.'' (We ascertained the estimated amount that would be paid in an earlier given year under the reasonable cost methodology and the estimated amount that would otherwise be paid without the

demonstration in an earlier given year from ''as submitted'' cost reports that were submitted by the hospitals prior to the inception of the demonstration.) We then updated the estimated cost described above to the current year by multiplying it by the market basket percentage increases applicable to the years involved and the applicable annual volume adjustment. For the FY 2010 IPPS/RY 2010 LTCH PPS final rule, data from finalized cost reports reflecting the participating hospitals' experience under the demonstration were available. Specifically, the finalized cost reports for the first 2 years of the demonstration, that is, cost reports for cost reporting years beginning in FYs 2005 and 2006 (CYs 2004, 2005, and 2006) were available. These data showed that the actual costs of the demonstration for these years exceeded the amounts originally estimated in the respective final rules for the budget neutrality adjustment. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we included in the budget neutrality offset amount an amount in addition to the estimate of the demonstration costs in that fiscal year. This additional amount was based on the amount that the costs of the demonstration for FYs 2005 and 2006 exceeded the budget neutrality offset amounts finalized in the IPPS rules applicable for those years.

Following upon the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we continued to propose a methodology for calculating the budget neutrality offset amount to account for both the estimated demonstration costs in the upcoming fiscal year and an 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) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. However, we noted in the FYs 2011, 2012, and 2013 IPPS final rules that, because of a delay affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we were unable to finalize this component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in a given year exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule for cost reports of demonstration hospitals dating to those beginning in FY 2007.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453), we adopted changes to the methodology for calculating the budget neutrality offset amount in an effort to further improve and refine the methodology. We noted that the revised methodology varied, in part, from the methodology finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51698 through 51705). We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453) for a detailed discussion of the methodology we used for FY 2013. We noted that, although we made changes to certain aspects of the budget neutrality offset amount calculation for FY 2013, several core components of the methodology remained unchanged. For example, we continued to include in the budget neutrality offset amount the estimate of the demonstration costs for the upcoming fiscal year and the amount by which the actual demonstration costs corresponding to an earlier year (which would be determined once we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50739 through 50744), we determined the final budget neutrality offset amount to be applied to the FY 2014 IPPS rates to be $52,589,741. This amount was comprised of two distinct components: (1) The final resulting difference between the total estimated FY 2014 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services, and the total estimated amount that would otherwise be paid to such hospitals in FY 2014 without the demonstration (this amount was $46,549,861); and (2) the amount by which the actual costs of the demonstration for FY 2007 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2007 for the 9 hospitals that participated in the demonstration during FY 2007) exceeded the budget neutrality offset amount that was finalized in the FY 2007 IPPS final rule (this amount was $6,039,880).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50141 through 50145), we determined the final budget neutrality offset amount to be applied to the FY 2015 IPPS rates to be $64,566,915. This amount was comprised of two distinct components: (1) The final resulting difference between the total estimated FY 2015 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services, and the total estimated amount that would otherwise be paid to such hospitals in FY 2015 without the demonstration (this amount was $54,177,144); and (2) the amount by which the actual costs of the demonstration for FY 2008 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2008 for the hospitals that participated in the demonstration during FY 2008) exceeded the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule (this amount was $10,389,771).

2. FY 2016 Budget Neutrality Offset Amount

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24518), in general, we proposed to use the established methodology used in FY 2015 (79 FR 50141 through 50145), with some modifications as discussed below, for determining the budget neutrality offset amount to be applied to the FY 2016 national IPPS rates to reflect the costs of the demonstration. We proposed to use ''as submitted'' cost reports ending in CY 2013 as the basis for estimating the reasonable cost amounts for covered services under the demonstration, as well as the amounts that would be paid absent the demonstration. As in previous years' IPPS rules, we believe that because these are the most recent available cost reports, they will be an accurate predictor of these amounts.

As discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24518), although the proposed methodology for FY 2016 is similar to that for the past several rules, we note that the demonstration will have begun to phase out by the beginning of FY 2016, and because of this, we believe additional calculations would be appropriate. The 7 ''originally participating hospitals,'' that is, those hospitals that began the demonstration between 2005 and 2009, will have ended their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. Therefore, we proposed that the financial experience of these hospitals would not factor into the estimated reasonable cost amount and the estimated amounts that would otherwise be paid without the demonstration for FY 2016.

The participation period for the 15 hospitals that entered the demonstration in 2011 and 2012 through the solicitation that followed the Affordable Care Act amendments expanding the demonstration program and that are still participating in the demonstration will end on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016, through December 31, 2016. As further discussed below, our proposed methodology for estimating the reasonable cost amounts for covered

inpatient hospital services under the demonstration, as well as the amounts that would otherwise be paid without the demonstration, would reflect the fact that some of the hospitals within this cohort will participate in the demonstration for only a fraction of the 12 months in FY 2016. Of the 15 hospitals that entered the demonstration in 2011 and 2012 under the Affordable Care Act expansion, 11 hospitals are scheduled to end the demonstration on or before September 30, 2016; 8 of these 11 hospitals are scheduled to end the demonstration prior to September 30, 2016.

For each of these 8 hospitals, we proposed that the FY 2016 estimated reasonable cost amount and the estimated amount that would otherwise be paid without the demonstration derived from the ''as submitted'' cost reports for cost reporting periods ending in CY 2013 be prorated according to the ratio of the number of months between October 1, 2015 and the end of the hospital's cost reporting period in relation to the entire 12-month period. (For example, if a hospital's cost reporting period end date is June 30, 2016, the factor to be multiplied by the estimated reasonable cost amount and the estimated amount that would otherwise be paid without the demonstration from the calendar year end 2013 cost report is 0.75.) For the 7 hospitals that would end the demonstration on either September 30, 2016 or December 31, 2016, estimates of these amounts would correspond to the amounts indicated in the calendar year end 2013 cost reports.

We note that the 7 hospitals that started the demonstration between FYs 2005 and 2009 also will have ended their participation on a rolling basis during FY 2015. In the FY 2015 IPPS/LTCH PPS final rule, in accordance with the policy we finalized in the FY 2015 IPPS/LTCH PPS final rule, we based the estimate of the cost of the demonstration for FY 2015 on the financial experience as indicated on these hospitals' CY 2012 ''as submitted'' cost reports (as discussed earlier) without making any adjustment to reflect the fact that hospitals would be ending at different points during FY 2015. We believe this methodology was reasonable because only 5 hospitals are ending their participation in the demonstration before September 30, 2015, out of the 22 hospitals on which the estimate of the cost of the demonstration for that year was based. Furthermore, as discussed previously, the methodology stated in this and previous rules for determining the costs of the demonstration in a given fiscal year entails the comparison of the actual costs of the demonstration as determined from finalized cost reports for that fiscal year (when they are available) to the estimated amount identified for that fiscal year in the corresponding fiscal year's final rule. Consistent with this policy, this second step will be used to reconcile any differences between the estimated and actual demonstration costs for FY 2015 once finalized cost reports for cost reporting periods beginning in FY 2015 are available. Although we believe that our methodology for estimating costs for FY 2015 was reasonable, for FY 2016, we proposed a more refined methodology to estimate the costs of the demonstration; that is, one that entails prorating, as discussed above, the estimated reasonable cost amount and the estimated amounts that would otherwise be paid without the demonstration as indicated on the ''as submitted'' cost reports for cost reporting periods ending in CY 2013 based on the number of months that each hospital will have participated in the demonstration during FY 2016.

Similar to previous years, we proposed the methodology for calculating the budget neutrality offset amount to proceed in several steps, as follows:

Step 1: For each of the 15 hospitals that will be participating in the demonstration during FY 2016, we proposed to identify the general reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services for the period of participation during FY 2016 based on ''as submitted'' cost reports ending in CY 2013. As discussed above, we proposed that the basis of this estimate for each hospital scheduled to participate for part of FY 2016 would be the fraction of the number of months that the hospital will be participating out of the 12 months within FY 2016 multiplied by the reasonable cost amount for covered inpatient hospital services indicated on the ''as submitted'' cost report ending in CY 2013.

Given that 8 hospitals will be participating in the demonstration for only part of FY 2016, we believe that such a methodology of prorating represents an appropriate refinement to the methodology established in previous rules for estimating the reasonable cost amount paid under the demonstration because each hospital's relevant cost experience, respectively, which this estimated amount reflects, would apply for the specific number of months for which it is participating in the demonstration in FY 2016. We believe that applying the relevant fraction, representing the number of months that the hospital will have participated during FY 2016 out of the 12 months in the fiscal year, will lead to more precise estimates.

Because section 410A of Public Law 108–173 stipulates that swing-bed services are to be included among the covered inpatient hospital services for which the demonstration payment methodology applies, we proposed to include the cost of these services, as reported on the ''as submitted'' cost reports ending in CY 2013 for the hospitals that provided swing-bed services in CY 2013, similarly prorated by the fraction of the number of months that the hospital will be participating out of the total number of months within FY 2016.

Similar to the methodology applied in FY 2015, we proposed to sum the two above-referenced amounts to calculate the general total estimated FY 2013 reasonable cost amount for covered inpatient hospital services for all participating hospitals. Next, we proposed to multiply the derived sum by the FY 2014, FY 2015, and FY 2016 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. We proposed to use the final FY 2016 IPPS market basket percentage increase in this final rule. We proposed to multiply this product of the prorated reasonable cost amount for all 15 hospitals (based on CY 2013 ''as submitted'' cost reports) and the market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment for FYs 2014, 2015, and 2016. The result was the proposed total estimated FY 2016 reasonable cost amount for covered inpatient hospital services for all hospitals participating in FY 2016.

We proposed to apply the IPPS market basket percentage increases applicable for FYs 2014 through 2016 to the reasonable cost amount derived from CY 2013 cost reports described earlier to model the estimated FY 2016 reasonable cost amount under the demonstration. We proposed to use the IPPS market basket percentage increases because we believe that these update factors appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology involved. The 3-percent annual volume adjustment was stipulated by the CMS Office of the Actuary and is being used because it is intended to reflect the tendency of hospitals' inpatient caseloads to increase. Because inpatient caseloads for small hospitals may fluctuate, we proposed to incorporate into the estimate of demonstration costs a factor

to allow for a potential increase in inpatient hospital services.

Step 2: For each of the 15 hospitals that will be participating in FY 2016, we proposed to identify the general estimated amount that would otherwise be paid in FY 2016 under applicable payment methodologies for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2013) if the demonstration was not implemented. Similar to Step 1, we proposed that the basis of this estimate for each hospital participating for part of FY 2016 would be the fraction of the number of months that the hospital will be participating out of the 12 months within FY 2016 multiplied by the estimated amount that would otherwise be paid for these services as indicated on the ''as submitted'' cost report ending in CY 2013. We believe that such a methodology of prorating represents an appropriate refinement to the methodology established in previous rules for estimating the amount that otherwise would be paid without the demonstration because each hospital's relevant costs and claims experiences, respectively, which this estimated amount reflects, would apply for the specific number of months for which it is participating in the demonstration in FY 2016. As we stated in Step 1, we believe that applying the relevant fraction, representing the number of months that the hospital will have participated during FY 2016 out of the 12 months in the fiscal year, will lead to more precise estimates.

Similarly, as in Step 1, for the hospitals that provide swing-bed services, we proposed to include the amount that would otherwise be paid for these services without the demonstration, as reported on the ''as submitted'' cost reports ending in CY 2013 for the hospitals that provided swing-bed services in CY 2013. We proposed to prorate, as appropriate, the estimated amount that would otherwise be paid for these services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2013) by the fraction of the number of months that the hospital will be participating in FY 2016 out of the total number of months within FY 2016, and include this amount in the total FY 2013 general estimated amount that would otherwise be paid for covered inpatient hospital services without the demonstration.

Similar to the methodology applied in FY 2015, we proposed to sum these two amounts and multiply the derived sum by the FYs 2014, 2015, and 2016 IPPS applicable percentage increases. We proposed to use the final FY 2016 applicable percentage increase in this final rule. This methodology differs from Step 1, in which we proposed to apply the IPPS market basket percentage increases to the sum of the hospitals' general total FY 2013 estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate update factors to estimate the amounts that would generally 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. We proposed then to multiply this product by a 3-percent annual volume adjustment for FYs 2014, 2015, and 2016. The result represents the proposed general total estimated FY 2016 amount that would otherwise be paid for covered inpatient hospital services without the demonstration to the hospitals that would be participating in FY 2016.

Step 3: We proposed to subtract the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the participating hospitals for covered inpatient hospital services for FY 2016 if the demonstration had not been implemented) from the amount derived in Step 1 (representing the sum of the estimated reasonable cost amount that generally would be paid under the demonstration to all participating hospitals for covered inpatient hospital services for FY 2016). We proposed that the resulting difference would represent one component of the estimated amount for which an adjustment to the FY 2016 national IPPS rates would be calculated (as further discussed below).

For the FY 2016 proposed rule, the resulting difference was $26,195,949 (80 FR 24520). This estimated amount was based on the specific assumptions identified regarding the data sources used, that is, ''as submitted'' recently available cost reports. We stated in the proposed rule that if updated data became available prior to the FY 2016 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to estimate the costs for the demonstration program in FY 2016. Therefore, we indicated that the estimated budget neutrality offset amount may change in the final rule, depending on the availability of updated data.

Step 4: We proposed to include in the budget neutrality offset amount the amount by which the actual demonstration costs corresponding to an earlier given year (which would be determined once we have finalized cost reports for that year) differs from the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. (In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50145), we calculated the amount by which the actual costs of the demonstration in FY 2008 exceeded the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule. The corresponding differences for FYs 2005, 2006, and 2007 were identified and included in the budget neutrality offset amounts in previous years' IPPS final rules.) At the time of development of the FY 2016 IPPS/LTCH PPS proposed rule, finalized cost reports for cost reporting periods beginning in FY 2009 were available for the 10 hospitals that completed a cost report period starting in FY 2009. These cost reports have been issued by the MACs as finalized, and they have been subjected to review processes specific to the calculations for cost-based payment as determined by the payment methodology for the demonstration. We note that CMS has issued a notice of reopening for several of these cost reports pertaining to an issue that affects hospitals nationwide. However, we stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24520) that it was not yet known if, or to what extent, the calculations for budget neutrality under the demonstration would be affected in the event of a reopening of these cost reports. Until such a determination is made, we indicated we believe that it would be appropriate to use these cost reports for our calculations under Step 4 for FY 2016 in order to take into account the actual costs of the demonstration for FY 2009 as soon as possible and to enhance the accuracy of the budget neutrality offset calculation (80 FR 24520).

Therefore, in the proposed rule, we identified the difference between the actual cost of the demonstration as indicated on these finalized FY 2009 cost reports and the budget neutrality offset amount that was identified in the FY 2009 IPPS final rule (73 FR 48670 through 48671), and we proposed to adjust the current year's budget neutrality offset amount by that difference. We stated that if there is a reopening that necessitates a recalculation for any of these reports, we would conduct another calculation once the affected cost reports are revised and finalized to determine the difference between the cost of the demonstration as reflected on the

revised and finalized cost reports and the amount that was included in the budget neutrality offset amount for FY 2009 as identified in the FY 2009 IPPS final rule (taking into account any amount already included in the finalized budget neutrality offset amount in this FY 2016 IPPS/LTCH PPS final rule that reflects an adjustment based on FY 2009 cost reports). We indicated that if finalized cost reports for demonstration hospitals that participated in FY 2010 or FY 2011 are available prior to this FY 2016 IPPS/LTCH PPS final rule, we intended to adjust the budget neutrality offset amount for FY 2016 for any amounts by which the finalized costs of the demonstration for the year (FY 2010 or FY 2011) differ from the amounts included in the budget neutrality offset finalized in the respective year's IPPS final rule that indicate the estimated cost of the demonstration for that fiscal year.

As further discussed below, we noted in the proposed rule that Step 4 would result in the amount indicating the actual cost of the demonstration for FY 2009 (determined from the current finalized FY 2009 cost reports described in Step 4) being less than the amount that was originally identified in the FY 2009 IPPS final rule as the estimated cost of the demonstration. Therefore, we proposed to include that component as a negative adjustment to the budget neutrality offset amount for FY 2016 (as explained below).

Step 5: The total budget neutrality offset amount that we proposed to apply in determining the budget neutrality adjustment to the FY 2016 IPPS rates used the sum of the amounts derived in Steps 3 and 4. Each of these amounts represents a discrete calculation, reflecting the two-stage process of ensuring budget neutrality for the demonstration: (1) Estimating the costs of the demonstration prospectively for the upcoming fiscal year from historical ''as submitted'' cost reports (Step 3), and (2) then retrospectively reconciling the difference between this estimate for a prior fiscal year and the actual costs as recorded on finalized cost reports for the specific fiscal year (Step 4).

Therefore, for the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24521), we proposed to incorporate the following components into the calculation of the total budget neutrality offset:

(a) The amount, derived from Step 3, representing the difference between the sum of the estimated reasonable cost amounts that would be paid under the demonstration to participating hospitals for covered inpatient hospital services for FY 2016 and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This amount would be based on ''as submitted'' cost reports for cost reporting periods ending in CY 2013, and would be prorated according to the number of months that each hospital will have participated in the demonstration in FY 2016 out of the 12-month fiscal year period. This amount was $26,195,949.

(b) The amount, as derived from Step 4, by which the actual costs of the demonstration for FY 2009 (as shown in the finalized cost reports for the 10 hospitals that completed a cost reporting period beginning in FY 2009) differ from the budget neutrality offset amount that was finalized in the FY 2009 IPPS final rule. Analysis of this set of cost reports shows that the budget neutrality offset amount that was finalized in the FY 2009 IPPS final rule exceeds the actual cost of the demonstration by $8,457,452.

For FY 2016, the total budget neutrality offset amount that we proposed to apply was the amount determined under item (a) of Step 5 ($26,195,949) minus the amount determined under item (b) of Step 5 ($8,457,452), or $17,738,497. We proposed to subtract the amount under item (b) from that under item (a) because the amount under item (b) represents the amount by which the budget neutrality offset finalized in the FY 2009 IPPS final rule exceeded the actual costs of the demonstration for FY 2009. Accordingly, we proposed to reduce the budget neutrality offset amount for FY 2016 by that amount (80 FR 24521).

We stated in the proposed rule that if updated data became available prior to this FY 2016 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to determine the budget neutrality offset amount for FY 2016. Therefore, we indicated that the amount of the budget neutrality offset may change in this FY 2016 IPPS/LTCH PPS final rule based on the availability of updated data. In addition, similar to previous years, we proposed that if finalized cost reports for all of the demonstration hospitals that participated in an applicable year (FY 2010 or FY 2011) are available prior to the FY 2016 IPPS/LTCH PPS final rule, we would adjust the budget neutrality offset amount to reflect the difference between the actual cost of the demonstration for the year (FY 2010 or FY 2011) and the budget neutrality offset amount applicable to such year as finalized in the respective year's final rule, as explained in Step 4. The resulting total would be the amount for which an adjustment to the national IPPS rates would be made.

We did not receive any public comments on our proposed budget neutrality offset methodology, as discussed above. Therefore, we are finalizing the FY 2016 budget neutrality offset methodology as proposed, with the modifications discussed below, that will be used to derive the respective components that comprise the budget neutrality offset amount for which the adjustment to the national IPPS rates is calculated for FY 2016.

Step 1: In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24521), we stated that if updated data became available prior to the FY 2016 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to determine the budget neutrality offset amount for FY 2016. We also stated that the budget neutrality offset amount may change in the final rule, based on the availability of updated data. In addition, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24519 through 24520), we proposed to use the final FY 2016 IPPS market basket percentage and the final FY 2016 applicable percentage increase in our calculation of the demonstration costs for FY 2016. Therefore, in order to derive the estimate of the demonstration costs for the 15 hospitals that will be participating in the demonstration during FY 2016 (that is, the difference between the estimate of the reasonable cost amount and the estimated amount that would otherwise be paid without the demonstration), we will use the final FY 2016 IPPS market basket percentage and applicable percentage increase provided by the CMS Office of the Actuary. These update factors are specified in section IV.A. of the preamble of this final rule. Accordingly, with this modification, the resulting estimate of costs of the demonstration for FY 2016 for the 15 hospitals participating in the demonstration in FY 2016 is $26,044,620, representing one component of the amount for which the adjustment to the national IPPS rates is calculated.

Step 2: We are identifying the difference between the actual cost of the demonstration for FY 2009 as indicated in the finalized cost reports for hospitals that participated in FY 2009 and that had cost reporting periods beginning in FY 2009 (this amount is $14,332,936), and the budget neutrality offset amount that was identified in the FY 2009 IPPS final rule (this amount is $22,790,388) (73 FR 48671). We are including that difference ($8,457,452) in the FY 2016 budget neutrality offset amount, as further explained below. As stated in

the proposed rule, if there is a reopening that necessitates a recalculation for any of these reports, we will conduct another calculation once the affected reports are revised and finalized to determine the difference between the costs of the demonstration as reflected in the revised and finalized cost reports and the amount that was included in the budget neutrality offset amount for FY 2009 as identified in the FY 2009 IPPS final rule (taking into account any amount already included in the finalized budget neutrality offset amount in the FY 2016 IPPS/LTCH PPS final rule that reflects an adjustment based on FY 2009 cost reports).

Step 3: In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24520 through 24521), we proposed that if finalized cost reports for demonstration hospitals that participated in FY 2010 or FY 2011 are available prior to the FY 2016 IPPS/LTCH PPS final rule, we would adjust the budget neutrality offset amount for FY 2016 to reflect the difference between the actual cost of the demonstration for the year (FY 2010 or FY 2011) and the amount included in the budget neutrality offset finalized in the respective year's IPPS final rule that indicates the estimated cost of the demonstration for that fiscal year. We have obtained finalized cost reports for cost reporting periods beginning in FY 2010 for the 9 hospitals whose cost reporting periods began in FY 2010, and thus are including in the budget neutrality offset amount for FY 2016 the difference between the actual cost of the demonstration in FY 2010 as indicated in these finalized cost reports, and the budget neutrality offset amount finalized for FY 2010 in the applicable IPPS final rule indicating the estimated cost of the demonstration for FY 2010. We discuss below several particular elements of the IPPS final rules for FYs 2010 and 2011 (74 FR 43922 through 43924 and 75 FR 50344 through 50345) that are relevant to conducting this analysis:

(a) The budget neutrality offset amount as set forth in the FY 2010 IPPS final rule (74 FR 43923 through 43924) included two different components. First, it included the estimate of the costs of the demonstration for FY 2010 for the 11 hospitals that were scheduled to participate in the demonstration as of the date the FY 2010 IPPS final rule was issued (this amount was $15,081,251). Second, the amounts by which the actual costs of the demonstration program in FYs 2005 and 2006, respectively, exceeded the budget neutrality offset amounts identified in the IPPS final rules for those years were incorporated as additional, discrete amounts into the budget neutrality offset amount for FY 2010 (we note that, because these amounts do not reflect the estimated demonstration costs for FY 2010, they are not included in our calculation under this Step 3).

(b) Given that when the FY 2010 IPPS final rule was published, the demonstration was expected to end in FY 2010, the estimate of the costs of the demonstration for FY 2010 for the 11 hospitals that were scheduled to participate in FY 2010 was calculated in the FY 2010 IPPS final rule using a prorating methodology similar to that described above for the estimate for FY 2016. Thus, the fraction of the number of months that the hospital was scheduled to participate in the demonstration during FY 2010 out of the 12-month fiscal year period served as the basis for estimating the reasonable cost amount that would be paid under the demonstration and the amount that would have been paid without the demonstration in FY 2010.

(c) Following upon the extension of the demonstration in 2010, as required by the Affordable Care Act, the FY 2011 IPPS final rule (75 FR 50344 through 50345) incorporated into the budget neutrality offset amount the estimated costs of the demonstration for FY 2010 that were not accounted for in the FY 2010 IPPS final rule because, in that final rule, we calculated the cost for FY 2010 assuming that for a subset of hospitals the demonstration would end before the end of that fiscal year. (This amount was $6,488,221.)

Therefore, the estimated costs of the demonstration for FY 2010 (and the budget neutrality offset amount relating to these costs) were finalized in the FYs 2010 and 2011 IPPS final rules, as discussed above. Accordingly, we are summing these two amounts, specified in the FYs 2010 and 2011 IPPS final rules ($15,081,251 and $6,488,221 respectively). This summed amount is $21,569,472. In this final rule, we are determining the difference between this amount and the actual costs of the demonstration in FY 2010. The actual cost of the demonstration in FY 2010 is determined from finalized cost reports for the hospitals that participated in the demonstration and that had cost reporting periods beginning in FY 2010; that amount is $16,817,922. Therefore, the estimated costs of the demonstration identified in the applicable final rules ($21,569,472) exceeded the actual costs of the demonstration ($16,817,922) by $4,751,550 for FY 2010.

Step 4: The amounts determined respectively in Steps 1, 2, and 3, each represent a discrete calculation, reflecting the following two-stage process of ensuring budget neutrality for the demonstration: (1) Estimating the costs of the demonstration prospectively for the upcoming fiscal year from historical cost reports (Step 1); and (2) then retrospectively reconciling the difference between this estimate for a prior fiscal year and the actual costs as recorded on finalized cost reports for the specific fiscal year (Steps 2 and 3). Therefore, for this FY 2016 IPPS/LTCH PPS final rule, we are incorporating the following components into the calculation of the total budget neutrality offset:

(a) The amount, derived from Step 1, representing the difference between the sum of the estimated reasonable cost amounts to be paid under the demonstration to participating hospitals for covered inpatient hospital services for FY 2016 and the sum of the estimated amounts that would generally be paid in FY 2016 if the demonstration had not been implemented. This amount is based on ''as submitted'' cost reports for cost reporting periods ending in CY 2013, and is prorated according to the number of months that each hospital will have participated in the demonstration in FY 2016 out of the 12-month fiscal year period. This amount is $26,044,620.

(b) The amount, as derived from Step 2, by which the actual costs of the demonstration for FY 2009 (as shown in the finalized cost reports for the 10 hospitals that completed a cost reporting period beginning in FY 2009) differ from the budget neutrality offset amount that was finalized in the FY 2009 IPPS final rule. Analysis of this set of cost reports shows that the budget neutrality offset amount that was finalized in the FY 2009 IPPS final rule exceeds the actual cost of the demonstration by $8,457,452 for FY 2009.

(c) The amount, as derived from Step 3, by which the actual costs of the demonstration for FY 2010 (as shown in the finalized cost reports for the 9 hospitals that completed a cost reporting period beginning in FY 2010) differ from the amount that was finalized as the costs of the demonstration for FY 2010 in the FYs 2010 and 2011 IPPS final rules. Analysis of this set of cost reports shows that the budget neutrality offset amount that was finalized to account for the demonstration costs in FY 2010 (as set forth in the FYs 2010 and 2011 IPPS final rules as discussed above) exceeds the actual cost of the demonstration for FY 2010 by $4,751,550.

For FY 2016, the total budget neutrality offset amount that we are applying to the national IPPS rates is:

The amount determined under item (a) of Step 4 ($26,044,620) minus the amount determined under item (b) of Step 4 ($8,457,452) minus the amount determined under item (c) of Step 4 ($4,751,550). We are subtracting the amounts under items (b) and (c) from that under item (a) because the amounts under items (b) and (c) represent the amount by which the budget neutrality offset finalized in the applicable IPPS final rules (FYs 2009, 2010, and 2011) exceeded the actual costs of the demonstration for FYs 2009 and 2010, respectively. Accordingly, we are reducing the budget neutrality offset amount under (a) of Step 4 by the amounts in (b) and (c) of Step 4, for a total FY 2016 budget neutrality offset amount of $12,835,618. This is the final budget neutrality offset amount for which the adjustment to the national IPPS rates for FY 2016 is calculated. (We discuss the final payment rate adjustment that is required to ensure budget neutrality of the demonstration program for FY 2016 (the budget neutrality adjustment factor) in section II.A.4.f. of the Addendum to this final rule.)

Finally, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24521), we indicated that we were considering whether to propose in future rulemaking that the calculation of the final costs of the demonstration for a fiscal year reflect that some of the participating hospitals would otherwise have been eligible for the payment adjustment for low-volume hospitals in that fiscal year if they had not participated in the demonstration. Our policy under the demonstration is that hospitals participating in the demonstration are not able to receive the low-volume payment adjustment in addition to the reasonable cost-based payment authorized by section 410A of Public Law 108–173. We refer readers to Change Request 7505, dated July 22, 2011, available on the CMS Web site at: *http://www.cms.gov*. Section 1886(d)(12) of the Act provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective FY 2005 (69 FR 49099 through 49102). We note that sections 3125 and 10314 of the Affordable Care Act provided for temporary changes in the qualifying criteria and payment adjustment for low-volume hospitals for FYs 2011 and 2012, which have been extended by subsequent legislation: Through FY 2013, by the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) (78 FR 50610 through 50613); through March 31, 2014, by the Pathway for SGR Reform Act (Pub L. 113–67) (79 FR 15022 through 15025); through March 31, 2015, by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) (79 FR 49998 through 50001); and most recently through September 30, 2017, by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10). The extension under section 204 of Public Law 114–10 is discussed in section IV.L. of the preamble of this final rule. These temporary changes have increased the number of hospitals that are eligible to receive the low-volume hospital payment adjustment.

To the extent a hospital would have received a low-volume hospital payment adjustment if it had not participated in the demonstration, we believe it would be reasonable to take this into account in future rulemaking in determining what the hospital would have otherwise been paid in an applicable year without the demonstration. Because this payment adjustment has not been factored into the estimation of payments that otherwise would have been paid under the demonstration, such a proposal would require detailed consideration of the data sources and methodology that would be used to determine which among the demonstration hospitals would have otherwise been eligible for the low-volume payment adjustment and to estimate the amount of the adjustment. We invited public comments on this issue.

We did not receive any public comments on this issue. We will continue to examine this issue and consider which data sources and methodology would be appropriate for determining which among the demonstration hospitals would have otherwise been eligible for the low-volume payment adjustment and for estimating the amount of that adjustment. We may address this issue again in the FY 2017 IPPS/LTCH PPS proposed rule.

We also intend to discuss in the FY 2017 IPPS/LTCH PPS proposed rule how we propose 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 will end December 31, 2016.

J. Changes to MS–DRGs Subject to the Postacute Care Transfer Policy (§ 412.4)

1. Background

Existing regulations at § 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. In the preamble to the FY 2006 IPPS 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 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. Changes to the Postacute Care Transfer MS–DRGs for FY 2016

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24522), we discussed that, based on our annual review of MS–DRGs, we had identified two proposed new MS–DRGs that we proposed to include on the list of MS–DRGs subject to the postacute care transfer policy. As we discussed in section II.G. of the preamble of the proposed rule (80 FR 24349 through 24410), in response to public comments and based on our analysis of FY 2014 MedPAR claims data, we proposed to make changes to MS–DRGs, effective for FY 2016.

As discussed in section II.G.3.b. of the preamble of the proposed rule (80 FR 24356 through 24361), we proposed to modify the MS–DRG assignment of certain cardiovascular procedures currently assigned to MS–DRGs 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Vessels/Stents), 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC), 248 (Percutaneous Cardiovascular Procedures with Non-Drug Eluting Stent with MCC or 4+ Vessels/Stents), 249 (Percutaneous Cardiovascular Procedures with Non-Drug Eluting Stent without MCC), 250 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC), and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent without MCC) to improve the clinical homogeneity of these MS–DRGs and reflect the resource cost of specialized equipment. We proposed to create new MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively) and to reassign the procedures performed within the heart chambers using intracardiac techniques from their existing assignment in MS–DRGs 246 through 251 to the two proposed new MS–DRGs.

To improve clinical coherence for the various cardiovascular procedures assigned to MS–DRGs 237 and 238 (Major Cardiovascular Procedures with and without MCC, respectively), as discussed in section II.G.3.e. of the preamble of the proposed rule (80 FR 24362 through 24379), we also proposed to delete MS–DRGs 237 and 238 and to create five new proposed MS–DRGs. Proposed new MS DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC and without MCC, respectively) would contain the more complex, more invasive aortic and heart assist procedures assigned to MS–DRGs 237 and 238. Proposed new MS–DRGs 270 (Other Major Cardiovascular Procedures with MCC), 271 (Other Major Cardiovascular Procedures with CC), and 272 (Other Major Cardiovascular Procedures without CC/MCC) would include the less complex, less invasive cardiovascular procedures assigned to MS–DRGs 237 and 238.

In light of these proposed changes to the MS–DRGs for FY 2016, according to the regulations under § 412.4(c), we evaluated these proposed MS–DRGs against the general postacute care transfer policy criteria using the FY 2014 MedPAR data. 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 procedures and/or diagnostic codes that would result in material changes to an MS–DRG. As a result of our review, we proposed to update the list of MS–DRGs that are subject to the postacute care transfer policy to include the proposed new MS–DRGs 273 and 274. We determined that existing MS–DRGs 246 through 251 do not qualify for the postacute care transfer policy and would not meet the review criteria for FY 2016. Proposed new MS–DRGs 268 through 272 also would not qualify for postacute care transfer policy status.

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals to update the list of MS–DRGs that are subject to the postacute care transfer policy to include new MS–DRGs 273 and 274. We omitted data for MS–DRGs 246 through 251 from the table published in the proposed rule (80 FR 24522 through 24523) and stated they did not meet review criteria. However, because we proposed changes to MS–DRGs 246 through 251 due to the reassignment of procedures to new MS–DRGs 273 and 274, we are including data for MS–DRGs 246 through 251 in the table in this final rule that show that MS–DRGs 246 through 251 do not qualify for the postacute care transfer policy for FY 2016. New MS–DRGs 268 through 272 also do not qualify for postacute care transfer policy status for FY 2016. The table below lists the MS–DRGs that are subject to the postacute care transfer policies for FY 2016.

LIST OF MS–DRGS THAT ARE SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS IN FY 2016

New MS–DRG	MS–DRG Title	Total cases	Postacute care transfers (55th percentile: 1,395)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.8005%)	Postacute care transfer policy status
246	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Vessels/Stents.	32,542	9,305	1,490	*4.5787	No.
247	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC.	85,648	8,054	669	*0.7811	No.

LIST OF MS–DRGS THAT ARE SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS IN FY 2016—Continued

New MS–DRG	MS–DRG Title	Total cases	Postacute care transfers (55th percentile: 1,395)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.8005%)	Postacute care transfer policy status
248	Percutaneous Cardiovascular Procedures with Non-Drug Eluting Stent with MCC or 4+ Vessels/Stents.	9,727	3,486	455	*4.6777	No.
249	Percutaneous Cardiovascular Procedures with Non-Drug Eluting Stent without MCC.	17,331	2,817	169	*0.9751	No.
250	Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC.	3,720	*1,094	183	*4.9194	No.
251	Percutaneous Cardiovascular Procedures without Coronary Artery Stent without MCC.	6,974	*799	51	*0.7313	No.
268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.	4,464	2,178	268	*6.0036	No.
269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.	19,382	3,617	0	*0	No.
270	Other Major Cardiovascular Procedures with MCC.	15,141	5,964	719	*4.7487	No.
271	Other Major Cardiovascular Procedures with CC.	10,368	4,027	532	*5.1312	No.
272	Other Major Cardiovascular Procedures without CC/MCC.	4,785	*880	54	*1.1285	No.
273	Percutaneous Intracardiac Procedures with MCC.	6,602	2,654	646	9.7849	Yes.
274	Percutaneous Intracardiac Procedures without MCC.	15,812	2,445	140	*0.8854	**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.

In addition, in the FY 2016 IPPS/LTCH PPS proposed rule, we determined that proposed new MS–DRGs 273 and 274 also would meet the criteria for the special payment methodology. Therefore, we proposed that the two proposed new MS–DRGs would be subject to the MS–DRG special payment methodology, effective FY 2016.

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal that new MS–DRGs 273 and 274 will be subject to the MS–DRG special payment methodology, effective FY 2016. The table below lists the MS–DRGs that are subject to the special payment policy for FY 2016.

LIST OF MS–DRGS THAT ARE SUBJECT TO SPECIAL PAYMENT POLICY FOR FY 2016

New 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
273	Percutaneous Intracardiac Procedures with MCC	6.1	$67,126	$60,588	Yes.
274	Percutaneous Intracardiac Procedures without MCC	2.6	0	0	*Yes.

*As described in the policy at 42 CFR 412.4(d)(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.

The postacute care transfer status and special payment policy status of these MS–DRGs are reflected in Table 5 associated with this final rule, which is listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site.

K. Short Inpatient Hospital Stays

We noted in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24523) that hospitals and physicians continue to voice their concern with parts of the 2-midnight rule finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954). We indicated that we were considering this feedback carefully, as well as recent MedPAC recommendations, and expected to include a further discussion of the broader set of issues related to short inpatient hospital stays, long outpatient stays with observation services, and the related −0.2 percent IPPS payment adjustment in the CY 2016 hospital outpatient prospective payment system proposed rule. We refer readers to the proposal and related discussion of these issues that were included in the CY 2016 OPPS/ASC proposed rule that appeared in the **Federal Register** on July 8, 2015 (80 FR 39348). We will respond to public comments received on these issues in response to the CY 2016 OPPS/ASC proposed rule in the CY 2016 OPPS/ASC final rule with comment period (which is expected to be issued in November 2015). To be assured consideration, public comments must be

submitted in response to the CY 2016 OPPS/ASC proposed rule, and received no later than 5 p.m. EST on August 31, 2015. The CY 2016 OPPS/ASC proposed rule contains further instructions on submitting public comments (80 FR 39200).

L. Interim Final Rule With Comment Period Implementing Legislative Extensions Relating to the Payment Adjustment for Low-Volume Hospitals and the Medicare-Dependent, Small Rural Hospital (MDH) Program

1. Recent Legislation

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10, enacted on April 16, 2015, extended the Medicare-dependent, small rural hospital (MDH) program as well as certain provisions relating to payment to low-volume hospitals under the IPPS. Section 204 of the MACRA extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS, originally provided for by the Affordable Care Act, for discharges occurring on or after April 1, 2015 through FY 2017 (September 30, 2017). Section 205 of the MACRA extended the MDH program for hospital discharges occurring on or after April 1, 2015 through FY 2017 (September 30, 2017). Due to the timing of the development of the FY 2016 IPPS/LTCH PPS proposed rule and the enactment of the MACRA, we were unable to address these legislative extensions in that proposed rule.

2. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

a. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital that is paid under IPPS beginning in FY 2005, and the low-volume hospital payment policy is set forth in the regulations at 42 CFR 412.101. Sections 3125 and 10314 of the Affordable Care Act provided for a temporary change in the low-volume hospital payment policy for FYs 2011 and 2012. Specifically, the provisions of the Affordable Care Act amended the qualifying criteria for low-volume hospitals to specify, for FYs 2011 and 2012, that a hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A during the fiscal year. In addition, the statute as amended by the Affordable Care Act, provides that the low-volume hospital payment adjustment (that is, the percentage increase) is to be determined using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year. We revised the regulations governing the low-volume hospital policy at § 412.101 to reflect the changes to the qualifying criteria and the payment adjustment for low-volume hospitals according to the provisions of the Affordable Care Act in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414).

The temporary changes to the low-volume hospital qualifying criteria and payment adjustment originally provided for by the Affordable Care Act have been extended by subsequent legislation as follows: Through FY 2013 by the American Taxpayer Relief Act of 2012 (ATRA), Public Law 112–240; through March 31, 2014, by the Pathway for SGR Reform Act of 2013, Public Law 113–167; through March 31, 2015, by the Protecting Access to Medicare Act of 2014 (PAMA), Public Law 113–93; and most recently through FY 2017 by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10. The extension provided by section 204 of the MACRA is discussed in greater detail in section IV.L.2.b. of the preamble of this interim final rule with comment period. For additional details on the implementation of the previous extensions, through March 31, 2015, of the temporary changes to the low-volume hospital qualifying criteria and payment adjustment originally provided for by the Affordable Care Act, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS notice (78 FR 14689 through 14691); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50611 through 50612); the FY 2014 IPPS interim final rule with comment period (79 FR 15022 through 15025); the FY 2014 IPPS notice (79 FR 34444 through 34446); and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49998 through 50001).

b. Implementation of Provisions of the MACRA for FY 2015

Section 204 of the MACRA provided for an extension of the temporary changes to the low-volume hospital qualifying criteria and payment adjustment for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). We addressed the extension of the temporary changes to the low-volume hospital payment policy for the last half of FY 2015, that is, for discharges occurring on or after April 1, 2015, through September 30, 2015, in instructions issued in Change Request 9197, Transmittals 3263 and 3281. (We note that Change Request 9197 was originally issued on May 22, 2015 as Transmittal 3263, and reissued on June 5, 2015 as Transmittal 3281 to correct a date in Attachment 3, draft Notification to Provider letter. All other information remained the same.) Generally, hospitals that were receiving the low-volume hospital payment adjustment for FY 2015 as of March 31, 2015 would continue to have low-volume hospital status for the second half of FY 2015, as long as the hospital continued to meet the applicable qualifying low-volume hospital criteria.

In the instructions issued in Change Request 9197, for discharges occurring on or after April 1, 2015, through September 30, 2015, consistent with the existing regulations at § 412.101(b)(2)(ii), we state that the same discharge data used for the low-volume adjustment for discharges occurring during the first half of FY 2015 will continue to be used for discharges occurring during the last half of FY 2015, as these data were the most recent available data at the time of the development of the FY 2015 payment rates. Specifically, for FY 2015 discharges occurring on or after April 1, 2015, through September 30, 2015, the low-volume hospital qualifying criteria and payment adjustment (percentage increase) is determined using FY 2013 Medicare discharge data from the March 2014 update of the MedPAR files. These discharge data can be found in Table 14 of the Addendum to the FY 2015 IPPS/LTCH PPS final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2015-IPPS-Final-Rule-Home-Page-Items/FY2015-Final-Rule-Tables.html*. We note that, consistent with past practice, Table 14 is a list of IPPS hospitals with fewer than 1,600 Medicare discharges and is not a listing of the hospitals that qualify for the low-volume adjustment for FY 2015; it does not reflect whether or not the hospital meets the mileage criterion (that is, the hospital must also be located more than 15 road miles from any other IPPS hospital). In order to receive the applicable low-volume hospital payment adjustment (percentage increase) for FY 2015 discharges, a hospital must meet both

the discharge and mileage criteria. We discuss the conforming changes to the regulations at § 412.101 consistent with the extension of the temporary changes to the low-volume hospital definition and payment adjustment provided by section 204 of the MACRA in section IV.L.2.c. of the preamble of this interim final rule with comment period.

c. Low-Volume Hospital Definition and Payment Adjustment for FY 2016

As discussed above, under section 1886(d)(12) of the Act, as amended by section 204 of the MACRA, the temporary changes in the low-volume hospital payment policy originally provided by the Affordable Care Act and extended through subsequent legislation, are effective through FY 2017. Under the prior extension, in accordance with section 105 of PAMA, those temporary changes in the low-volume hospital payment policy were to be in effect for discharges on or before March 31, 2015 only. Due to the timing of the development of the FY 2016 IPPS/LTCH PPS proposed rule and the enactment of the MACRA, we were unable to address the extension of the changes in the low-volume hospital payment policy for FY 2016 (or the last half of FY 2015, as discussed in section IV.L.2.b. of the preamble of this interim final rule with comment period) in that proposed rule. In this interim final rule with comment period, we are revising the regulations at § 412.101 to conform to the provisions of section 204 of the MACRA.

To implement the low-volume hospital payment adjustment for FY 2016 consistent with provisions of the MACRA, in accordance with existing § 412.101(b)(2)(ii) and consistent with our historical approach, we are updating the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase). Under existing § 412.101(b)(2)(ii), for the applicable fiscal years, a hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, are used to determine if the hospital meets the discharge criteria to receive the low-volume payment adjustment in the current year. The applicable low-volume percentage increase, as originally provided for by the Affordable Care Act, is determined using a continuous linear sliding scale equation that results in a low-volume hospital payment adjustment ranging from an additional 25 percent for hospitals with 200 or fewer Medicare discharges to a zero percent additional payment adjustment for hospitals with 1,600 or more Medicare discharges. For FY 2016, consistent with our historical policy, qualifying low-volume hospitals and their payment adjustment will be determined using the most recently available Medicare discharge data from the March 2015 update of the FY 2014 MedPAR file, as these data are the most recent data available. Table 14 listed in the Addendum of the FY 2016 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp*) lists the ''subsection (d)'' hospitals with fewer than 1,600 Medicare discharges based on the claims data from this FY 2014 MedPAR file and their potential low-volume payment adjustment for FY 2016. Consistent with past practice, we note that this list of hospitals with fewer than 1,600 Medicare discharges in Table 14 does not reflect whether or not the hospital meets the mileage criterion. Eligibility for the low-volume hospital payment adjustment for FY 2016 also will be dependent upon meeting the mileage criterion specified at § 412.101(b)(2)(ii); that is, the hospital must be located more than 15 road miles from any other IPPS hospital. In other words, eligibility for the low-volume hospital payment adjustment for FY 2016 also is dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2015) or continuing to meet (in the case of a hospital that did qualify for the low-volume hospital payment adjustment in FY 2015) the mileage criterion specified at revised § 412.101(b)(2)(ii) (that is, the hospital is located more than 15 road miles from any other subsection (d) hospital).

In order to receive a low-volume hospital payment adjustment under § 412.101 for FY 2016, consistent with our previously established procedure, a hospital must notify and provide documentation to its MAC that it meets the discharge and distance requirements under § 412.101(b)(2)(ii), as revised. Specifically, for FY 2016, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2015, in order for the applicable low-volume hospital payment adjustment to be applied to payments for its FY 2016 discharges occurring on or after October 1, 2015. Under this procedure, a hospital that qualified for the low-volume payment adjustment in FY 2015 may continue to receive a low-volume payment adjustment for FY 2016 without reapplying if it continues to meet the Medicare discharge criterion established for FY 2016 and the mileage criterion. However, the hospital must send written verification that is received by its MAC no later than September 1, 2015, stating that it continues to be more than 15 miles from any other ''subsection (d)'' hospital. This written verification could be a brief letter to the MAC stating that the hospital continues to meet the low-volume hospital distance criterion as documented in a prior low-volume hospital status request. If a hospital's written request for low-volume hospital status for FY 2016 is received after September 1, 2015, and if the MAC determines that 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 the payment for the hospital's FY 2016 discharges, effective prospectively within 30 days of the date of its low-volume hospital status determination, consistent with past practice.

(For additional details on our established process for the low-volume hospital payment adjustment, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50000 through 50001).)

In this interim final rule with comment period, we are making conforming changes to the existing regulations text at § 412.101 to reflect the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2017 (that is, through September 30, 2017) in accordance with section 204 of the MACRA. In general, these conforming changes consist of replacing the phrase ''through FY 2014, and the portion of FY 2015 before April 1, 2015'' with ''through FY 2017'' each place it appears, and replacing the phrase ''the portion of FY 2015 beginning on April 1, 2015, and subsequent fiscal years'' with the phrase ''FY 2018 and subsequent fiscal years'' each place it appears. Specifically, we are revising paragraphs (b)(2)(i), (b)(2)(ii), (c)(1), (c)(2), and (d) of § 412.101. Under these revisions to § 412.101, beginning with FY 2018, consistent with section 1886(d)(12) of the Act, as amended, the low-volume hospital qualifying criteria and payment adjustment methodology will revert to that which was in effect prior to the amendments made by the Affordable Care Act and subsequent legislation (that is, the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010).

3. Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

a. Background for MDH Program

Section 1886(d)(5)(G) of the Act provides special payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (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).)

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 as follows: First, section 606 of the ATRA (Pub. L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013). Second, section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) extended the MDH program through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Third, section 106 of the PAMA (Pub. L. 113–93) extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Most recently, section 205 of the MACRA (Pub. L. 114–10) extended the MDH program though FY 2017 (that is, for discharges occurring before October 1, 2017). For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414); the FY 2013 IPPS notice (78 FR 14689); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649); the FY 2014 interim final rule with comment period (79 FR 15025 through 15027); the FY 2014 notice (79 FR 34446 through 34449); and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022 through 50024).

b. MACRA Provisions for Extension of the MDH Program

Section 205 of the MACRA provided for an extension of the MDH program for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Specifically, section 205 of the MACRA amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act by striking ''April 1, 2015'' and inserting ''October 1, 2017''. Section 205 of the MACRA also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act.

In this interim final rule with comment period, we are making conforming changes to the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the extension of the MDH program provided for by the MACRA. Due to the timing of the development of the FY 2016 IPPS/LTCH PPS proposed rule and the enactment of the MACRA, we were unable to address the extension of the MDH program for FY 2016 (or the last half of FY 2015) in that proposed rule. After the MACRA was enacted, we addressed the extension of the MDH program for the last half of FY 2015 (that is, for discharges occurring on or after April 1, 2015, through September 30, 2015) in instructions issued in Change Request 9197, Transmittals 3263 and 3281. (We note that Change Request 9197 was originally issued May 22, 2015 as Transmittal 3263, and reissued June 5, 2015 as Transmittal 3281 to correct a date in Attachment 3, draft Notification to Provider letter. All other information remained the same.)

As explained in Change Request 9197, consistent with the previous extensions of the MDH program and the regulations at § 412.108, generally, a provider that was classified as an MDH as of March 31, 2015, was reinstated as an MDH effective April 1, 2015, 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 April 1, 2015, the effective date of MDH status may not be retroactive to April 1, 2015. For more details regarding MDH status for the second half of FY 2015, we refer the reader to Change Request 9197.

4. Responses to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge and respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this document, and, when we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

5. Waiver of Notice of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act. In addition, in accordance with section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act, we ordinarily provide a delay in the effective date of a substantive rule. For substantive rules that constitute major rules, in accordance with 5 U.S.C. 801, we ordinarily provide a 60-day delay in the effective date. None of the processes or effective date requirements apply, however, when the rule in question is interpretive, a general statement of policy, or a rule of agency organization, procedure, or practice. They also do not apply when the statute establishes rules to be applied, leaving no discretion or gaps for an agency to fill in through rulemaking. In addition, an agency may waive notice-and-comment rulemaking, as well as any delay in effective date, when the agency for good cause finds that notice and public comment on the rule as well the effective date delay are impracticable, unnecessary, or contrary to the public interest. In cases where an agency finds good cause, the agency must incorporate a statement of this finding and its reasons in the rule issued.

Sections 204 and 205 of the MACRA require the agency to make the changes to the payment adjustment for low-volume hospitals and the MDH program set forth in sections IV.B. and C. of the preamble of this interim final rule with comment period, effective April 1, 2015 through September 30, 2017. We are conforming our regulations at § 412.101 and § 412. 108 to specific statutory requirements contained in sections 204 and 205 of the MACRA or that directly result from those statutory requirements and informing the public of the procedures and practices the agency will follow to ensure compliance with those statutory provisions. To the extent that notice-and-comment rulemaking or a delay in effective date, or both, would otherwise apply, we believe that there is good cause to waive such requirements and to implement the requirements of section 204 and 205 of the MACRA through an interim final rule with comment period. Specifically, we find it unnecessary to undertake notice-and-comment rulemaking in this instance because this interim final rule with comment period sets forth the requirements for the extension of the temporary changes to the payment adjustment for low-volume hospitals and the extension of the MDH program as prescribed by the MACRA, as well as procedures and practices that directly result from those statutory requirements. As changes related to requirements of section 204 and 205 of the MACRA outlined in this interim final rule with comment period have already taken effect, it also would be impracticable to undertake notice-and-comment rulemaking.

For the reasons outlined, we find good cause to waive the notice of proposed rulemaking for the requirements for the extension of the temporary changes to the payment adjustment for low-volume hospitals and the extension of the MDH program as prescribed by the sections 204 and 205 of the MACRA and implement these provisions on an interim final basis. Even though we are waiving notice of proposed rulemaking requirements and are issuing these provisions on an interim basis, we are providing a 60-day public comment period. For these reasons, we also find that a waiver of any delay in effective date, if it were otherwise applicable, is necessary to comply with the requirements of section 204 and 205 of the MACRA. Therefore, we find good cause to waive notice-and-comment procedures as well as any delay in the effective dates for these MACRA requirements.

6. Collection of Information Requirements

This interim final rule with comment period does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

7. Impact of Legislative Extensions

a. Effects of the Payment Adjustment for Low-Volume Hospitals for FY 2016

Based on the latest available data, we estimate that approximately 593 hospitals will qualify as a low-volume hospital in FY 2016. We project that the extension for FY 2016 of the temporary changes to the low-volume hospital definition and the payment adjustment methodology provided for by the MACRA will result in an increase in payments of approximately $322 million in FY 2016 as compared to payments to qualifying hospitals without the extension of the temporary changes to the low-volume hospital definition and the payment adjustment methodology.

b. Effects of the Extension of the MDH Program for FY 2016

As discussed above, in this interim final rule with comment period, we are making conforming changes to the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the extension of the MDH program provided for by the MACRA. Hospitals that qualify as MDHs receive the higher of operating IPPS payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the amount by which the hospital-specific rate (a hospital-specific cost-based rate) exceeds the Federal standardized amount. Based on the latest available data we have for 163 MDHs, we project that 90 MDHs will receive the blended payment (that is, the Federal standardized amount plus 75 percent of the amount by which the hospital-specific rate exceeds the Federal standardized amount) for FY 2016. We estimate that those hospitals will experience an overall increase in payments of approximately $96 million as compared to payments they would have received had the MDH program not been extended for FY 2016.

V. 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. The IPPS for capital-related costs was initially implemented in the Federal fiscal year (FY) 1992 IPPS final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period 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 § 412.312 of the regulations. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at § 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, § 412.300(b) of the regulations defines 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. Hospitals Located in Puerto Rico

Section 412.374 of the regulations provides for the use of a blended payment amount for prospective payments for capital-related costs to

hospitals located in Puerto Rico. Accordingly, under the capital IPPS, we compute a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital-related costs. In general, hospitals located in Puerto Rico are paid a blend of the applicable capital IPPS Puerto Rico rate and the applicable capital IPPS Federal rate. Capital IPPS payments to hospitals located in Puerto Rico are computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. For additional details on capital IPPS payments to hospitals located in Puerto Rico, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

C. Annual Update for FY 2016

The annual update to the capital PPS Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), for FY 2016 is discussed in section III. of the Addendum to this final rule.

We note that, in section II.D. of the preamble of this final rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the recoupment adjustment to the standardized amounts under section 1886(d) of the Act that we are finalizing for FY 2016 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 631 of the ATRA. Because section 631 of the ATRA requires CMS to make a recoupment adjustment only to the operating IPPS standardized amount, we are not making a similar adjustment to the national or Puerto Rico capital IPPS rates (or to the operating IPPS hospital-specific rates or the Puerto Rico-specific standardized amount). This approach is consistent with our historical approach regarding the application of the recoupment adjustment authorized by section 7(b)(1)(B) of Public Law 110–90.

VI. Changes for Hospitals Excluded From the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals for FY 2016

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 applies as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare payments for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, RNHCIs also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed above.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update the target amounts for short–term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. As we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), we will continue to use the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts 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 for FY 2016 and subsequent fiscal years. Accordingly, for FY 2016, the rate-of-increase percentage to be applied to the target amount for these 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 is the FY 2016 percentage increase in the FY 2010-based IPPS operating market basket.

For the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24525), based on IHS Global Insight, Inc.'s 2015 first quarter forecast, we estimated that the FY 2010-based IPPS operating market basket update for FY 2016 was 2.7 percent (that is, the estimate of the market basket rate-of-increase). We indicated in the proposed rule that if more recent data became available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2016. For this FY 2016 IPPS/LTCH PPS final rule, based on IHS Global Insight, Inc.'s 2015 second quarter forecast (which is the most recent data available), we calculated the FY 2010-based IPPS operating market basket update for FY 2016 to be 2.4 percent. Therefore, the FY 2016 rate-of-increase percentage that is applied to the FY 2015 target amounts in order to calculate the FY 2016 target amounts 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 is 2.4 percent, in accordance with the applicable regulations at 42 CFR 413.40.

B. Report on Adjustment (Exceptions) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, adjusting, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested in order to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we are publishing data on adjustment payments that were processed by the MAC or CMS during FY 2014.

The table below includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2014. As indicated above, the adjustments made during FY 2014 only pertain to cost reporting periods ending in years prior

to FY 2013. Total adjustment payments given to excluded hospitals during FY 2014 are $1,515,104. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of hospital	Number	Excess cost over ceiling	Adjustment payments
Children's	1	$1,140,682	$829,567
Cancer	.....	.....	.....
Religious Nonmedical Health Care Institution (RNHCI)	2	729,557	685,537
Total	3	1,870,239	1,515,104

C. Out of Scope Comments Relating to Critical Access Hospitals (CAHs) Inpatient Services

In response to the FY 2016 IPPS/LTCH PPS proposed rule, we received the following public comment relating to conditions for payment for inpatient services furnished in critical access hospitals (CAHs), which we consider to be outside of the scope of the FY 2016 proposed rule.

One commenter specifically addressed the requirement that, for inpatient CAH services to be payable under Medicare Part A, a physician must certify that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH (section 1814(a)(8) of the Act; 42 CFR 424.15). The commenter stated that this certification is inconsistent with the congressional intent of the CAH program and should be eliminated. The commenter stated that CAHs provide high quality and cost-efficient care, which allows Medicare beneficiaries living in rural areas to receive this care close to home. The commenter noted that some CAHs have established general surgery programs, which allow senior citizens to receive surgical services in a nearby and familiar location. However, the commenter believed that the 96-hour certification requirement for payment of inpatient services furnished in a CAH prohibits CAHs from receiving payment for providing these surgical services.

We acknowledge the commenter's concerns. However, because we did not specifically propose any changes related to the 96-hour certification requirement for CAH inpatient services, we consider this comment to be outside the scope of the proposed rule and are not addressing the comment at this time. We note that the 96-hour certification requirement was last addressed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50163 through 50165).

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2016

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 defines 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 also provides an alternative definition of LTCHs: specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

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

VII. of the preamble of this final 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).

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51733 through 51743) for a chronological summary of the main legislative and regulatory developments affecting the LTCH PPS through the annual update cycles prior to the FY 2014 rulemaking cycle. In addition, in this rule, we discuss the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, and the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–97), enacted on March 27, 2014, both of which affect the LTCH PPS. In section VII.B. of the preamble of this final rule, we discuss our finalized policies to implement the provisions of section 1206(a) of Public Law 113–67, which amended section 1886(m) of the Act by adding paragraph (6) and established, among other things, patient-level criteria for payments under the LTCH PPS for implementation beginning with FY 2016, and our changes to the calculation of the greater than 25-day average length of stay criteria, consistent with the statute, in section VII.F. of the preamble of this final rule. In section VII.E. of the preamble of this final rule, as discussed in the preamble, we are finalizing several technical clarifications relating to our implementation of the new statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities (subject to certain defined exceptions) and the new statutory moratorium on bed increases in existing LTCHs under section 1206(b)(2) of Public Law 113–67, as amended.

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)(I) 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. Alternatively, § 412.23(e)(2)(ii) states that, for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days.

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) or 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).
- 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 light of our finalized policies to implement section 1206(a) of Public Law 113–67, we also need to address beneficiary charges in the context of the new site neutral payment rate. Therefore, in section VII.B.7.c. of the preamble of this final rule, we are finalizing proposals to amend the existing regulations relating to the limitation on charges to address beneficiary charges under the new LTCH PPS payment rate.

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services for which a claim is submitted other than in an electronic form specified by the Secretary. Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two

specific types of cases and may also waive such denial in such unusual cases as the Secretary finds appropriate (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified under 45 CFR parts 160 and 162 (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct certain electronic health care transactions according to the applicable transactions and code sets standards.

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of health information technology and promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) leads these efforts in collaboration with other agencies, including CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Through a number of activities, including several open government initiatives, HHS is promoting the adoption of electronic health record (EHR) technology certified under the ONC Health Information Technology (HIT) Certification Program developed to support secure, interoperable, health information exchange. The HIT Policy Committee (a Federal Advisory Committee) has recommended areas in which HIT certification under the ONC HIT Certification Program would help support providers that are eligible for the Medicare and Medicaid EHR Incentive Programs, such as long-term care and postacute care hospitals and behavioral health care providers. We believe that the use of certified EHRs by LTCHs (and other types of providers that are ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support the exchange of important information across care partners and during transitions of care, and could enable the reporting of electronically specified clinical quality measures (eCQMs) (as described elsewhere in this rule). More information on the ONC HIT Certification Program and efforts to develop standards applicable to LTCHs can be found by accessing the following Web sites and resources:

- *http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf*;
- *http://www.healthit.gov/facas/FACAS/health-it-policy-committee/hitpc-workgroups/certificationadoption*;
- *http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG*; and
- *http://wiki.siframework.org/Longitudinal+Coordination+of+Care*.

B. Application of the Site Neutral Payment Rate (New § 412.522)

1. Overview

Section 1206 of Public Law 113–67 mandates significant changes to the payment system for LTCHs beginning with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Under the current LTCH PPS, all discharges are paid under the LTCH PPS standard Federal payment rate (that is, payments calculated under the existing regulations, including adjustments, in Subpart O of 42 CFR part 412). Section 1206 requires the establishment of an alternate ''site neutral'' payment rate for Medicare inpatient discharges from an LTCH that fail to meet certain statutorily defined criteria. Discharges that meet the criteria will continue to be paid the LTCH PPS standard Federal payment rate. Discharges that do not meet the statutory criteria will be paid at a new site neutral payment rate, as described below. We note that, for the remainder of this section, the phrase ''LTCH PPS standard Federal payment rate case'' refers to an LTCH PPS case that meets the criteria for exclusion from the site neutral payment rate under section 1886(m)(6)(A)(ii) of the Act as discussed in section VII.B.3. of the preamble of this final rule, and the phrase ''site neutral payment rate case'' refers to an LTCH PPS case that does *not* meet the statutory patient-level criteria and, therefore, is paid the applicable site neutral payment rate in accordance with section 1886(m)(6)(A)(i) of the Act, as discussed in section VII.B.4. of the preamble of this final rule.

Under section 1886(m)(6)(A) of the Act as added by section 1206(a) of Public Law 113–67, beginning in cost reporting periods starting on or after October 1, 2015, all LTCH discharges are paid according to the site neutral payment rate unless certain criteria are met. For LTCH cases that meet the criteria for exclusion, the site neutral payment rate does not apply and payment is made without regard to the provisions of section 1886(m)(6) of the Act. For cases that meet the criteria for exclusion from the site neutral payment rate, payment will continue to be based on the LTCH PPS standard Federal payment rate as determined in § 412.523. As discussed in section VII.B.3. of the preamble of this final rule, under section 1886(m)(6)(A)(ii) of the Act, the criteria for exclusion from the site neutral payment rate are: (1) The discharge from the LTCH does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; (2) admission to the LTCH was immediately preceded by discharge from a subsection (d) hospital; and (3) the immediately preceding stay in a subsection (d) hospital included at least 3 days in an intensive care unit (ICU) (referred to in this final rule as the ICU criterion) or the discharge from the LTCH is assigned to a MS–LTC–DRG based on the patient's receipt of ventilator services of at least 96 hours (referred to in this final rule as the ventilator criterion).

In this section of the final rule, we discuss our proposed and finalized policies to implement the required changes to the LTCH PPS payment rate, as well as other related finalized policy provisions in accordance with section 1206(a) of Public Law 113–67 under the broad authority of section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA.

2. Application of the Site Neutral Payment Rate Under the LTCH PPS

For FY 2016, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24527), we proposed to add a new section to the regulations under 42 CFR part 412 Subpart O (new § 412.522) to establish the site neutral payment rate required by section 1886(m)(6) of the Act as added by section 1206(a)(1) of Public Law 113–67. Specifically, section 1886(m)(6) of the Act requires that, beginning in cost reporting periods occurring on or after October 1, 2015, all LTCH discharges are paid under the site neutral payment rate unless certain criteria are met. All LTCH discharges that meet the criteria for exclusion from the site neutral payment rate will continue to be paid the LTCH PPS standard Federal payment rate. Accordingly, in this final rule, under the broad authority of section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA and in accordance with section 1206(a) of Public Law 113–67, we are establishing policies to implement the statutory criteria for excluding cases from the site neutral payment rate under new § 412.522(b), as well as establish the requirements for determining the site neutral payment rate for a given LTCH discharge under new § 412.522(c) (as discussed in detail below).

In addition, we proposed certain changes to § 412.521 in light of our

implementation of the site neutral payment rate under new § 412.522 (80 FR 24527). We did not receive any public comments on our proposed changes to § 412.521, and are adopting these proposals as final, without modification. Specifically, we are finalizing conforming changes to paragraph (a)(2) of § 412.521 to include the new site neutral payment rate established in accordance with new § 412.522 as a method of payment under the LTCH PPS. We also are finalizing a technical change to the language in § 412.521(a)(2) that currently refers to the Federal payment rate by changing the term from ''Federal payment rate'' to ''standard Federal payment rate'' in order to provide consistent terminology when referring to such a payment.

Comment: Many commenters objected to the application of the new site neutral payment rate. Some commenters expressed concern that wound care is not categorically excluded from the application of the new site neutral payment rate and requested that CMS create such a categorical exclusion. Some of these commenters also requested that a study of the relative outcomes of wound care in LTCHs and other settings be conducted. Other commenters requested that CMS pay differently for site neutral payment rate cases treated in rural LTCHs, and recommended paying these hospitals for services performed on a cost basis similar to critical access hospitals (CAHs), or comparably to inpatient rehabilitation facilities (IRFs).

Response: While we acknowledge that the new site neutral payment rate will be lower than the historic standard Federal payment rate for certain LTCH discharges, we do not have the authority to establish regulatory payment policy exceptions to pay rural LTCHs at any rate other than what is provided under the new dual payment rate structure under the LTCH PPS. Further, under the LTCH PPS we do not have the authority to pay anything other than the site neutral payment rate for any LTCH discharge that does not meet the exclusion criteria. The statute explicitly established the dual payment rate structure, which expressly provides that payment for all LTCH discharges will be calculated based on the new site neutral payment rate, unless the LTCH discharge meets the statutorily defined exclusion criteria to be paid based on the LTCH PPS standard Federal payment rate. Because the new site neutral payment rate and the exclusions apply to all LTCH discharges, further legislation would be required if we were to pay any rate other than the site neutral payment rate, or, where the exceptions to that rate apply, the LTCH PPS standard Federal payment rate. Furthermore, Congress did not provide any authority within the statute to delay implementation of the new dual rate LTCH PPS payment structure to allow time for a study to assess the relative outcomes of wound care in LTCHs compared to other settings. We note that CMS is currently engaged in many quality assessment initiatives, including in LTCHs and other postacute settings. In light of that ongoing work, we do not have current plans to conduct a separate study limited to outcomes for wound care cases in different settings. Further information on our quality initiatives is available on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/index.html*.

Comment: Several commenters expressed concerns that exclusion from the lower site neutral payment rate may be dependent upon events that may be outside of the LTCH's control. For example, the commenters stated that an LTCH would have no control over when a subsection (d) hospital submitted its claim for the immediately preceding subsection (d) hospital discharge, or whether an immediately preceding subsection (d) hospital discharge claim would contain a coding error such that the claim would fail to indicate that the patient received ICU services for at least 3 days. Given this lack of control, commenters expressed concern about our setting the LTCH PPS payment rates based in part upon the content of the subsection (d) hospital's claim.

Response: We expect LTCHs and their referring hospitals to be closely engaged with each other in coordination of care efforts with regard to their referred patients. As part of these working relationships, we encourage each party to effectively communicate and exchange information to help ensure that LTCH claims are paid appropriately. We acknowledge the commenters' concerns. The new dual payment rate structure is, by statute, premised on events which occurred prior to the admission to the LTCH. We must look at what happens or did not happen in the immediately preceding subsection (d) hospital inpatient stay, and we believe that the IPPS claim is the best existing source of accurate and complete information for events which occurred during the IPPS hospital inpatient stay.

In fact, we have considered the issues raised by the commenters in our development of the claims processing systems changes needed to implement the new dual rate LTCH PPS payment structure. We believe that these claims processing systems changes will appropriately identify all LTCH discharges, consistent with the statutory requirements under the new dual rate LTCH PPS payment structure, based on the best available data at the time the LTCH discharge claim is processed. Furthermore, our operational design of the claims processing system requirements under this new dual rate LTCH PPS payment structure also includes automatic prompts to appropriately adjust the LTCH PPS payment for an LTCH case if there is a change in either the subsection (d) hospital's claim information or the LTCH's claim information that would result in any change in payment (that is, from the site neutral payment rate to the LTCH PPS standard Federal payment rate or vice versa), consistent with the statutory criteria.

However, we acknowledge that, as this is a new payment structure, it may not work flawlessly in each and every instance. In those rare instances where an obvious error occurs in the determination of the LTCH PPS payment amount for a particular case, LTCHs can contact their MACs and we will reevaluate our available information to ensure that the correct payment is made under current policies. We appreciate ongoing feedback from hospitals concerning ways to make these processes more efficient and cost effective, while continuing to ensure that LTCH claims are paid appropriately. As we gain experience under the revised LTCH PPS, we may modify some of our operational approaches.

Comment: One commenter requested that CMS provide additional payment under the LTCH PPS for end-stage renal disease (ESRD) patients under the same circumstances as under the IPPS, noting that section 1881(b) of the Act does not limit the adjustment to subsection (d) hospitals. The commenter believed that information included in its comment and an analysis previously provided to CMS supported its request for this additional payment amount.

Response: Although we consider this comment to be outside the scope of the proposed rule, we note that we responded to the same suggestion in a detailed response in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50767). As discussed in that final rule, based on our analysis of FY 2012 LTCH PPS claims data, the costs of treating ESRD patients in LTCHs are adequately reflected in data used to determine the MS–LTC–DRG relative weights for nondialysis MS–LTC–DRGs, and that the additional resources associated with

renal dialysis treatments are included in the LTCH PPS payments. Because the commenters failed to present any new evidence to contradict those conclusions, we continue to believe that the standard Federal payment rate accounts for these costs. Furthermore, as we discuss in section VII.B.7.b. of the preamble of this final rule, until we gain experience with the effects and implementation of the new site neutral payment rate and the types of cases paid at this rate, we believe that it is premature to consider whether additional payments are either necessary or appropriate. We may revisit this issue in the future, if data demonstrate such a change is warranted for either LTCH PPS standard Federal payment rate cases or site neutral payment rate cases.

Comment: A few commenters expressed appreciation for the information added to the publically available FY 2014 LTCH MedPAR File for the proposed rule which identifies whether the LTCH discharge in the historical data is site neutral payment rate case or standard payment rate case (that is, meets the criteria for exclusion from the site neutral payment rate) had the new statutory patient criteria been in effect at the time of the discharge. Some commenters also requested additional information be added to the publically available IPPS & LTCH PPS MedPAR files, such as encrypted patient identifiers, and encrypted admission and discharge dates, along with the number of days the patient spent in the ICU in the immediately preceding IPPS hospital stay prior to admission to the LTCH. These commenters believe that such additional information is needed to determine which historical discharges were immediately preceded by a qualifying IPPS hospital stay and could be used to verify the payment rate designation (that is, site neural or standard) CMS has included in the publically available LTCH MedPAR file.

Response: We understand that for commenters that would like to replicate the proposed LTCH PPS rates, factors and payment estimates presented in the proposed rule, it is necessary to be able to identify the LTCH discharges in the historical data that would be standard payment rate cases and the ones that would be site neutral payment rate cases (had the statutory criteria been in effect at the time of the discharge). We are also aware that currently the publically available IPPS and LTCH PPS MedPAR files do not contain any specified direct patient identifiers consistent with CMS's privacy and security standards and as outlined in the HIPAA Privacy Rule. (For additional information on CMS' privacy and security standards under the HIPAA Privacy Rule, we refer readers to the CMSWeb site at: *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAGenInfo/PrivacyandSecurityStandards.html*, and for additional information on CMS' publically available Limited Data Set (LDS) files, we refer readers to the CMS Web site at: To *http://cms.hhs.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/index.html*.) It is for these reasons that, as noted by commenters, we added an identifier to the publically available FY 2014 LTCH MedPAR File to identify the historical LTCH discharges in that file as standard payment rate cases or site neutral payment rate cases (had the statutory dual rate LTCH PPS payment structure been in effect at the time of the discharge). These are the same payment rate identifiers we used to develop the FY 2016 proposed rates, factors and payment estimates as described in the proposed rule. We believe that the addition of this payment rate identifier to the publically available LTCH MedPAR file provides sufficient information for commenters to replicate and evaluate the proposed rates, factors and payment estimates in the proposed rule. We considered adding the encrypted information requested by commenters to the publically available IPPS and LTCH PPS MedPAR files; however, we are not able to do so at this time because to add such specific direct patient identifiers would need to be done in conformance with CMS's privacy and security standards, including any requirements outlined in the HIPAA Privacy Rule. We are, however, adding the information on the number of days the patient spent in the ICU in an immediately preceding IPPS hospital stay prior to admission to the LTCH, as requested by commenters, since this aggregated count of days conforms with CMS's privacy and security standards because it does not result in the identification of specific beneficiaries. We believe including the count of days in the ICU from the immediately preceding IPPS hospital stay to the publically available MedPAR file will allow the public to adequately corroborate the indicator of the historical LTCH discharges as a standard payment rate case or a site neutral payment rate cases (had the statutory criteria been in effect at the time of the discharge).

3. Criteria for Exclusion From the Site Neutral Payment Rate

a. Statutory Provisions

As stated earlier, section 1206(a) of Public Law 113–67 amended section 1886(m) of the Act by adding paragraph (6), which specifies that beginning in cost reporting periods starting on or after October 1, 2015, all LTCH PPS discharges will be paid based on the site neutral payment rate unless certain criteria are met. In general, under section 1886(m)(6)(A)(ii) of the Act, the criteria for exclusion from the site neutral payment rate are: The discharge from the LTCH does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, the admission to the LTCH was immediately preceded by discharge from a subsection (d) hospital, and that immediately preceding stay in a subsection (d) hospital included at least 3 days in an intensive care unit (ICU) (referred to in this final rule as the ICU criterion) or the discharge from the LTCH is assigned to an MS–LTC–DRG based on the patient's receipt of at least 96 hours of ventilator services during the LTCH stay (referred to in this final rule as the ventilator criterion). Below we summarize our proposals and the public comments received, and provide our responses to those comments and the finalized policies to implement the statutory criteria for exclusion from the site neutral payment rate.

b. Implementation of the Criterion for a Principal Diagnosis Relating to a Psychiatric Diagnosis or to Rehabilitation

Section 1886(m)(6)(A)(ii)(II) of the Act specifies that in order for an LTCH discharge to be excluded from payment under the site neutral payment rate, the LTCH discharge cannot have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation. To implement this criterion, under the broad authority of section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA and in accordance with section 1206(a) of Public Law 113–67, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24528 through 24529), we proposed to identify cases with a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation that would be assigned to specific MS–LTC–DRG groupings that we believe indicate such principal diagnoses using the most recent version of the MS–LTC–DRGs. We invited public comments on our proposed approach and our proposed list of applicable MS–LTC–DRGs.

Comment: Several commenters supported our proposal to identify discharges with a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation using the specific MS–LTC–DRGs included in our proposal.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing without change our proposal to identify discharges with a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation that are assigned to the specific MS–LTC–DRG groupings included in our proposal using the most recent version of the MS–LTC–DRGs. (For additional information on the version of the MS–DRGs, and by extension the MS–LTC–DRGs, that is Version 33, we refer readers to section II.G. of the preamble of this final rule.)

Accordingly, as we proposed, we are establishing that an LTCH discharge assigned to one of the following ICD–10 MS–LTC–DRG groupings in the most recent version of the MS–LTC–DRGs (that is, Version 33 for FY 2016) will be identified as a case with a principal diagnosis relating to a psychiatric diagnosis:

- MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnosis of Mental Illness);
- MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction);
- MS–LTC–DRG 881 (Depressive Neuroses);
- MS–LTC–DRG 882 (Neuroses except Depressive);
- MS–LTC–DRG 883 (Disorders of Personality & Impulse Control);
- MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation);
- MS–LTC–DRG 885 (Psychoses);
- MS–LTC–DRG 886 (Behavioral & Developmental Disorders);
- MS–LTC–DRG 887 (Other Mental Disorder Diagnoses);
- MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama);
- MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy);
- MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); and
- MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC).

Furthermore, as we proposed, we also are establishing that an LTCH discharge assigned to one of the following ICD–10 MS–LTC–DRG groupings in the most recent version of the MS–LTC–DRGs (that is, Version 33 for FY 2016) will be identified as an LTCH discharge with a principal diagnosis relating to rehabilitation:

- MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and
- MS–LTC–DRG 946 (Rehabilitation without CC/MCC).

Under this finalized policy, as we proposed, an LTCH discharge grouped to any of the MS–LTC–DRG groupings listed above will not meet the criteria under new § 412.522(b)(1)(i) to be excluded from the site neutral payment rate.

c. Addition of Definition of a ''Subsection (d) Hospital'' to LTCH Regulations

The site neutral payment rate established in section 1206(a) of Public Law 113–67 includes several references to ''subsection (d) hospitals.'' The term ''subsection (d) hospital'' is defined in section 1886(d)(1)(B) of the Act as a hospital that is located in 1 of the 50 States or the District of Columbia that is not a psychiatric hospital, a rehabilitation hospital, a children's hospital, an LTCH, or a cancer hospital. However, section 1886(m)(6)(D) of the Act, as added by section 1206(a)(1) of Public Law 113–67, added that, for LTCH PPS purposes, any reference to a ''subsection (d) hospital'' is deemed to include a ''subsection (d) Puerto Rico hospital,'' which is defined by section 1886(d)(9)(A) of the Act (providing that the term ''subsection (d) Puerto Rico hospital'' means a hospital that is located in Puerto Rico and that would be considered a subsection (d) hospital (as defined in paragraph (d)(1)(B)) if it were located in 1 of the 50 States).

Given these statutory provisions, as part of our implementation of section 1206(a) of Public Law 113–67, and under the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24529), we proposed to add a definition of the term ''subsection (d) hospital'' to § 412.503 (defined as any hospital qualifying as a subsection (d) hospital under section 1886(d)(1)(B) of the Act and any hospital located in Puerto Rico that would be qualified as a subsection (d) hospital under section 1886(d)(1)(B) of the Act if it were located in 1 of the 50 States).

Comment: Several commenters supported the proposed definition of a ''subsection (d) hospital'' under the LTCH PPS.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to add the proposed definition for a ''subsection (d) hospital'' under § 412.503, without change.

d. Interpretation of ''Immediately Preceded'' by a Subsection (d) Hospital Discharge

Section 1886(m)(6)(A)(ii)(II) of the Act specifies that, in order to be excluded from payment under the site neutral payment rate, the LTCH discharge must meet the ICU criterion at section 1866(m)(6)(A)(iii) of the Act or the ventilator criterion at section 1866(m)(6)(A)(iv) of the Act. Both the ICU criterion and the ventilator criterion require that the LTCH admission be ''immediately preceded'' by a discharge from a subsection (d) hospital. Therefore, under the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24529 through 24530), we proposed to define the phrase ''immediately preceded'' in the context of a discharge from a subsection (d) hospital. Specifically, we proposed that the discharged Medicare patient would have to depart the subsection (d) hospital and arrive for admission to the LTCH without having returned home or being admitted to any other inpatient setting, including an IRF, an IPF, or a SNF. As required by the statute, we proposed that any LTCH admission that did not qualify under this definition as having been ''immediately preceded'' by a discharge from a subsection (d) hospital would not be eligible to qualify for exclusion from the site neutral payment rate based on the ICU or the ventilator criterion. We proposed to codify these proposals at new § 412.522(b)(1)(ii).

To implement these policies, we proposed to look at the Medicare patient's discharge date on the subsection (d) hospital's claim, and compare it to the admission date on the LTCH's Medicare claim for the patient. In doing so, we proposed that the discharge date had to have occurred on the same date as the LTCH admission (or, for those rare circumstances where a patient is discharged from a subsection (d) hospital before the midnight census, but was not admitted to the LTCH until after the midnight census of that date of discharge, the day before the calendar date of the LTCH admission) if a patient's discharge were to qualify as being immediately preceded by a discharge from a subsection (d) hospital.

We also proposed to condition eligibility for exclusion from the site neutral payment rate on the immediately preceding subsection (d) hospital's claim using of certain codes,

namely Patient Discharge Status Code 63, which signifies a patient was discharged or transferred to an LTCH, or Patient Discharge Status Code 91, which signifies a patient was discharged/transferred to a Medicare-certified LTCH with a planned acute care hospital inpatient readmission.

In making these proposals, we also noted that our proposed interpretation of ''immediately preceded'' by a subsection (d) hospital would work in tandem with our existing interrupted stay policy at § 412.531. An interruption of stay occurs when, during the course of an LTCH hospitalization, the patient is discharged to an inpatient acute care hospital, an IRF, or a SNF for treatment for a service that is not available at the LTCH for a specified period followed by readmittance within a specified number of days to the same LTCH. In such cases, the care following readmission is considered a continuation of the care interrupted by the first discharge, so both ''halves'' of the LTCH episode of care are bundled, and Medicare makes a single payment based on the second date of discharge. As the two halves constitute a single episode of care, the discharge that is relevant to determining if that episode of care was immediately preceded by the required subsection (d) hospital stay is the care provided prior to the first admission to the LTCH. Using these concepts, any interruption of stay defined under § 412.531 would not invalidate the immediately preceded status for the single episode of care—only the care provided prior to the first LTCH admission would be relevant.

Comment: Some commenters generally supported CMS' proposal to define the phrase ''immediately preceded'' in the context of the subsection (d) hospital discharge occurring on the same calendar date as the LTCH admission (or, in certain rare circumstances, the calendar date before the date of the LTCH admission). However, many commenters expressed concern with CMS' proposal to require specific patient discharge status codes on the subsection (d) hospital claim. These commenters believed that reliance on these status codes was unnecessary, given the high percentage of LTCH admissions that occur on the same date as preceding subsection (d) hospital discharges, and noted that there is inconsistency in the use of discharge status codes by subsection (d) hospitals. The commenters also believed that it would be difficult and burdensome for LTCHs to get information from the referring hospital regarding the discharge status code. Some of these commenters suggested that CMS determine whether the immediately preceding requirement for LTCH discharges paid at the LTCH PPS standard Federal payment rate is met solely from information provided by the LTCH, such as through some form of self-attestation.

Response: After considering the comments we received, we believe that reliance on the discharge and admission dates may adequately address our concerns and, therefore, we agree that requiring the presence of specific discharge status code(s) on the preceding subsection (d) hospital claim as a condition of qualifying for the exclusions from the site neutral payment rate may not be necessary at this time. We considered continuing to require the discharge status codes when LTCH admission occurred the day after the subsection (d) hospital discharge, which would allow additional time for intervening services to be received by the patient. However, the commenters' analyses showed that between 95 percent and 99 percent of LTCH admissions that occur within 1 day of a subsection (d) hospital discharge occur on the same date as the subsection (d) hospital discharge and provides adequate protection against inappropriate payments at this time. Based on this assessment, we are not finalizing the discharge status code requirements at this time. However, we may revisit this issue in future rulemaking, and may propose changes to this policy if reliance on the discharge and admission dates prove inadequate to determine appropriate payment. We also are taking this opportunity to remind all hospitals of their responsibility to bill accurately, including the use of the appropriate patient discharge status codes. Regarding the specific suggestions that we determine immediately preceding discharges based solely on LTCH claims, we do not believe such an approach would serve as adequate protection against misuses and inappropriate payments under the new dual rate LTCH PPS payment structure. We believe that claims data, which hospitals submit for Medicare payment, should be a reliable data source upon which to base a determination of whether an immediately preceding subsection (d) hospital stay occurred. When such reliable primary source data are available, we see little reason to rely on a secondary source, such as an LTCH conveying assurances of an immediately preceding discharge. We do not believe that it would be appropriate to rely upon, either presumptively or otherwise, an attestation or assertion about what the LTCH's may believe occurred in the previous subsection (d) hospital admission, when more reliable data are available directly from the subsection (d) hospital that delivered that preceding care rather than in our claims processing systems.

After consideration of the public comments we received, we are finalizing our proposed policy that conditions eligibility for exclusion from the site neutral payment rate on the LTCH admission having been ''immediately preceded'' by a subsection (d) hospital stay, as evidenced by the admission to the LTCH occurring either on the date of or, in certain rare circumstances, the calendar date after the discharge from the preceding subsection (d) hospital. As discussed above, we are not finalizing our proposals regarding the discharge status codes as reported on the preceding subsection (d) hospital's claim. As finalized at new § 412.522(b)(1)(ii), an LTCH discharge will be considered to have been immediately preceded by a discharge from a subsection (d) hospital if there was a direct admission from such a hospital, as evidenced by the dates of discharge and admission, to the LTCH.

e. Implementation of the Intensive Care Unit (ICU) Criterion

Section 1886(m)(6)(A)(iii)(I) of the Act specifies that in order to be excluded from payment under the site neutral payment rate under the ICU criterion, the LTCH admission must be immediately preceded by a discharge from a subsection (d) hospital that included at least 3 days in an intensive care unit (ICU), as determined by the Secretary. In doing so, section 1886(m)(6)(A)(iii)(II) of the Act requires the use of data from revenue center codes 020X or 021X (or such successor codes as the Secretary may establish). As discussed in the proposed rule (80 FR 24530), revenue center codes are reported on the hospital claim with revenue center code 020X (indicating intensive care), and the revenue center code 021X (indicating coronary care). Both of these revenue center codes are used to bill Medicare for services provided by ''intensive care units (ICUs)'' as defined under our existing definition at § 413.53(d) of the regulations, and, as indicated by the ''X'' in the revenue code descriptions both are further divided into subcategories that form a revenue center code series.

As described in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24530), we proposed to implement the ICU criterion under new § 412.522(b)(2). In that section, we proposed that the claim

from the subsection (d) hospital that immediately preceded the admission to the LTCH had to indicate receipt of at least 3 days of care in an ICU using revenue center codes 020X or 021X (or such successor code as the Secretary may establish), the use of which must be consistent with our definition of an ICU under § 413.53(d), in order to fulfill the ICU criterion for exclusion from the site neutral payment rate. We re refer readers to the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24530) for more information on the development of our proposal for the implementation of the ICU criterion under section 1886(m)(6)(A)(iii) of the Act, including our explanation as to why we believe that our proposed implementation of the ICU criterion will work in tandem with our existing LTCH policies governing interrupted stays. As we noted in the context of our ''immediately preceded'' policy discussion above, because the two halves of an interrupted stay constitute a single episode of care (as shown by the issuance of a single payment), the discharge that is relevant to determining if that episode of care was immediately preceded by a subsection (d) hospital stay that included 3 days in the ICU is the first admission to the LTCH.

Comment: Some commenters generally supported CMS' proposal to use the presence or absence of revenue center codes 020X or 021X on the preceding subsection (d) hospital claim as the basis for concluding that an LTCH admission was or was not preceded by a subsection (d) hospital stay including at least 3 days in the ICU, and, based on that finding, whether the LTCH admission was eligible for exclusion from the site neutral payment rate. Some commenters opined that CMS lacks the authority to exclude certain subsets of these codes. Other commenters disagreed with the proposal to rely on the subsection (d) hospital's reporting of these revenue center codes because doing so would increase administrative burdens imposed upon subsection (d) hospitals and LTCHs. Some commenters recommended that CMS adopt a policy by which compliance would be determined based solely on the information an LTCH submitted on its claims, others suggested reliance on self-attestation. Others suggested specific focus on, and the adoption of indicators based on, the severity of a patient's illness rather than relying on the use of revenue center codes. Some commenters also disagreed with CMS' proposal to define an ICU stay in a manner that required the subsection (d) hospital's adherence to § 413.53(d), asserting that there was no statutory basis for such a requirement.

Response: We appreciate the commenters' suggestions, but we disagree with the commenters who asserted we lacked the authority to exclude certain subsets of revenue center codes. The statute merely requires us to use data from the sequences of revenue center codes, not every code within the sequences. We also disagree with commenters who asserted that there is no legal obligation to require consistency between the use of revenue center codes 020X or 021X for purposes of determining LTCH PPS payment rates and the subsection (d) hospital's coding of its claim in a manner that complies with our definition of ICU services under § 413.53(d). Hospitals must comply with all applicable requirements when they submit a claim for Medicare reimbursement. Section 1886(m)(6)(A)(iii) of the Act does not exempt subsection (d) hospitals from any of the requirements that govern their delivery of services, or their billing for those services. As such, the requirements governing their use of revenue center codes 020X or 021X on their claims are unchanged by our policy to use those codes as the basis for determining exclusion of an LTCH discharge from the site neutral payment rate. Furthermore, we also disagree with the commenters who suggested it would be appropriate to determine compliance with the ICU criterion based solely on data obtained from an LTCH's claim. Congress expressly mandated that the ICU criterion was to be based on events that occurred prior to the LTCH admission. The best source of data for what happened in a subsection (d) hospital is that subsection (d) hospital, and the information needed to determine ICU exclusion eligibility should be readily available on any properly billed subsection (d) hospital claim. Furthermore, given the potential for audit, and the penalties for filing false claims, we believe that claims data should be a reliable data source upon which to make a determination for exclusion from the site neutral payment rate under the ICU criteria. When such reliable primary source data is available, we see little reason to rely on a secondary source such as an LTCH conveying its understanding of the services received at the preceding subsection (d) hospital at the time of patient transfer. We do not believe that it would be appropriate to rely upon, presumptively or otherwise, assertions about the LTCH's understanding about the previous medical care received by the patient, when more reliable data is available directly from the subsection (d) hospital that provided that care in our claims processing systems. Again, as discussed above, we recognize the commenters' concerns and have in fact considered these issues in our development of claims processing systems changes to implement the new system. We believe that these systems changes will allow for appropriate payment for all LTCH discharges under the new dual rate LTCH PPS payment structure. As part of the relationship between referring IPPS hospitals and LTCHs, we encourage each party to communicate and exchange information to help ensure that LTCH claims are paid appropriately. While final payment of the LTCH claim will be based in part on information from preceding subsection (d) hospital's IPPS claim, we would encourage LTCHs to ask questions of the referring hospitals in order to ascertain all necessary information prior to admitting a patient. We may revisit these issues as we gain more experience under the revised LTCH PPS particularly if we observe an unusual change in hospital ICU coding behavior or if we become aware of data which demonstrates that use of particular codes within the 020X or 021X are inappropriate bases for meeting the ICU criterion. We do, however, acknowledge that as this is a new payment structure, it may not work flawlessly in each and every instance. In those rare instances where obvious errors occur in the determination of the LTCH PPS payment amount for a particular case, LTCHs can contact their MACs and we will recheck our available information to ensure that correct payments are made under our policies.

Comment: One commenter requested clarification of how the proposals to implement the ICU criterion would interact with CMS' existing interrupted stay policy.

Response: As we previously noted in our discussion of our policies regarding the ''immediately preceded'' requirement, our dual rate LTCH PPS payment structure policies were designed to complement our existing interrupted stay policies. Both halves of an interrupted stay constitute a single episode of care (as demonstrated by the issuance of a single payment). As such interrupted stays have historically been treated as a single episode of care, we established in this final rule that the relevant subsection (d) hospital discharge for purposes of the payment of interrupted stays under the dual rate LTCH PPS payment structure is the first subsection (d) discharge. Under this policy, any time spent in a subsection

(d) hospital's ICU during an interrupted LTCH stay would not be considered in the evaluation of whether the interrupted LTCH stay met the ICU criterion because such care would not have immediately preceded the initial admission to the LTCH. Conversely, if the subsection (d) hospital discharge that immediately preceded the initial LTCH admission meets the ICU criterion (that is, includes at least 3 ICU days), and the period of time relating to an intervening interrupted stay does not include any days in a subsection (d) hospital's ICU, the ICU criterion would still be met because the initial LTCH admission fulfilled the ICU criterion for exclusion from the site neutral payment rate. However, we note that if the intervening stay in the acute care hospital is 10 days or longer (such that our interrupted stay policy would be inapplicable with respect to the readmission to the LTCH), in order for the second admission to meet the ICU criterion to be excluded from the site neutral payment rate, the acute care hospital stay would have to include at least 3 days in an ICU.

After consideration of the public comments we received, we are finalizing without modification our proposal that at least 3 days of ICU services must be reported on the preceding subsection (d) hospital claim using revenue center codes 020X or 021X, and that such coding must be consistent with our policies governing ICU services under § 413.53(d) in order for an LTCH discharge to fulfill the requirements of the ICU criterion for exclusion from the site neutral payment rate. As we proposed, we are codifying this policy under new § 412.522(b)(2).

f. Implementation of the Ventilator Criterion

Section 1886(m)(6)(A)(vi) of the Act specifies that in order to be excluded from payment under the site neutral payment rate under the ventilator criterion, the LTCH admission must be immediately preceded by a discharge from a subsection (d) hospital (as discussed in section VII.B.3.d. of the preamble of this final rule), and the LTCH discharge must be assigned to an MS–LTC–DRG based on the beneficiary's receipt of at least 96 hours of ventilator services in the LTCH. As we discussed in the preamble of the proposed rule (80 FR 24531), we proposed that, for the purposes of a discharge being excluded from the site neutral payment rate based on the ventilator criterion, the discharge must use the applicable procedure code to indicate that at least 96 hours of ventilator services were received during the LTCH stay. Currently, under the ICD–9–CM coding system, procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more) is used to describe such long-term mechanical ventilator services. As discussed in sections II.G.1.a. and VII.C. of the preamble of this final rule, the use of the ICD–10–CM/PCS coding system is required beginning October 1, 2015. Under the ICD–10–PCS coding system, procedure code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours) describes such long-term mechanical ventilator services. Therefore, we further proposed, effective with discharges in cost reporting periods beginning on or after October 1, 2015, to determine if a discharge meets the requirements of the ventilator criterion in order to be eligible for exclusion from the site neutral payment rate based on whether the LTCH reports procedure code 5A1955Z on its hospital claim. If finalized, we proposed to place these requirements under new § 412.522(b)(3).

Under this proposal, any LTCH claims that do not report this procedure code would not meet the requirements of the ventilator criterion in order to be eligible for exclusion from the site neutral payment rate. For more detail regarding the ventilator criterion proposals and the alternatives that we had considered in developing those proposals (including the use of MS–LTC–DRGs in lieu of this procedure code), we refer readers to the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24531).

Comment: Commenters generally supported CMS' proposal to determine whether an LTCH discharge meets the ventilator criterion based on the use of ICD–10–PCS procedure code 5A1955Z. However, some commenters expressed concern that CMS' proposal failed to identify and include cases that receive *exactly* 96 hours of ventilator services. The commenters pointed out that, under the statutory language, cases representing patients receiving *exactly* 96 hours of ventilation should also be paid the LTCH PPS standard Federal payment rate, assuming the other relevant criteria are met. Some commenters suggested that discharges identified by ICD–10–PCS procedure code 5A1945Z (Continuous invasive mechanical ventilation, 24—96 consecutive hours) and were grouped into one of the six long-term mechanical ventilator MS–LTC–DRGs (that is, MS–LTC–DRGs 003, 004, 207, 870, 927, 933) should also be used as an additional procedure code to identify discharges meeting the ventilator criterion. Doing so, they believed, would ensure proper payment of cases that received *exactly* 96 hours of ventilator services. Other commenters noted their belief that the statute does not require consecutive hours on ventilator services and, therefore, were concerned that the use of ICD–10–PCS procedure code 5A1945Z, which they believed specified more than 96 hours of *continuous* ventilation, would not recognize discharges that receive 96 hours or more of *noncontinuous* of ventilator services. For example, the commenters indicated that ICD–10–PCS procedure code 5A1945Z may not appropriately account for hours used during ventilator weaning, which could discourage LTCHs from weaning patients off of ventilator services within less than 96 hours, if the number of hours provide during the weaning process would result in less than 96 hours of services being provided.

Response: The commenters are correct in noting that the range of consecutive hours for mechanical ventilation services under the ICD–10–PCS differs from the ICD–9–CM, with the primary difference being the handling of the 96th hour. The ICD–9–CM system provides three unique procedure codes for mechanical ventilator services based on the number of consecutive hours: ICD–9–CM procedure code 96.70 for an unspecified duration of service, ICD–9–CM procedure code 96.71 for services less than 96 consecutive hours in duration, and ICD–9–CM procedure code 96.72 for services consisting of 96 consecutive hours or more. Whereas, the ICD–10–PCS provides three unique codes for mechanical ventilator services based on the number of consecutive hours with the following ranges: services consisting of less than 24 consecutive hours (ICD–10–PCS procedure code 5A1935Z); services consisting of 24 to 96 consecutive hours (ICD–10–PCS procedure code 5A1945Z); and services consisting of greater than 96 consecutive hours (ICD–10–PCS procedure code 5A1955Z). Consequently, under the ICD–10–PCS, mechanical ventilation services in duration of exactly 96 hours are no longer grouped in the same range as services consisting of more than 96 hours, as it is under ICD–9–CM system.

We have considered the commenters' suggestions. While we agree that our proposed use of procedure code 5A1945Z would not identify a case where the patient received *exactly* 96 hours of ventilator services and that such a case should be paid the LTCH PPS standard Federal payment rate. Despite that, for the reasons noted below, we continue to believe that the

most appropriate means of implementing the ventilator criterion is by the use of ICD–10–PCS procedure code 5A1955Z.

We first considered the commenters' suggested alternative method, but determined that it was not a viable option because, under the ICD–10 coding guidelines and Version 33.0 MS–DRGs (discussed in section II.G.1.a. of this preamble) and by extension the MS–LTC–DRGs, discharges with ICD–10–PCS procedure code 5A1945Z (Respiratory ventilation, 24–96 consecutive hours), but not ICD–10–PCS procedure code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours), will not be grouped into any of the MS–LTC–DRGs suggested by the commenters. That is, the commenters' suggested alternative is not possible because the GROUPER logic for those MS–LTC–DRGs only includes ICD–10–PCS procedure code 5A1955Z. Furthermore, based on existing claims elements and ICD–10–PCS procedure codes' descriptions, we were unable to identify any feasible alternative procedure code to identify a case where the patient received *exactly* 96 hours of ventilator services, and the commenters did not provide any data or anecdotal evidence of such situations regularly occurring. We do not believe that many patients receive exactly 96 hours of ventilator services, and we expect that this problem will rarely, if ever, arise. However, if these rare instances occur, the LTCH should contact its MAC to have the appropriate LTCH PPS payment amount under the new dual rate LTCH PPS payment structure determined for any such claims (which should be coded with the appropriate use of ICD–10–PCS procedure code 5A1945Z).

With respect to the commenters' concerns regarding counting the number of hours in which a patient is being weaned from mechanical ventilator services, the AHA Coding Clinic (4th Quarter 2014) instructs coders that, in general, ''[w]hen the patient is being weaned from mechanical ventilation, the entire duration of the weaning process is counted to determine the correct code assignment.'' We also refer readers to the AHA Coding Clinic guidelines, which provide guidance on determining the duration of mechanical ventilation services, including any weaning period. Therefore, we do not believe that the use of ICD–10–PCS procedure code 5A1955Z, which specifies more than 96 hours of continuous ventilation, would discourage LTCHs from weaning patients of a ventilator in less than 96 hours because the use of this procedure code accounts for hours spent during the ventilator weaning process. However, we remind providers that providing medically unnecessary services to patients (including additional time on a ventilator in order to meet the requirements for exclusion from the site neutral payment rate) and reporting charges for such services constitutes fraudulent behavior for which we will monitor. We also intend to continue to monitor the appropriateness of the use of ICD–10–PCS procedure code 5A1955Z, and may propose alternative implementation measures for the ventilator criterion to the extent experience under the revised LTCH PPS demonstrates such action is necessary.

After consideration of the public comments we received, we are finalizing our proposal, without modification, and codifying our ventilator criterion under new § 412.522.

4. Determination of the Site Neutral Payment Rate (New § 412.522(c))

a. General

Section 1206(a) of Public Law 113–67 amended section 1886(m) of the Act by adding paragraph (6), which specifies that beginning with cost reporting periods starting on or after October 1, 2015, all LTCH PPS discharges are paid according to the site neutral payment rate unless certain criteria are met. In general, section 1886(m)(6)(B)(ii) of the Act specifies that the site neutral payment rate is the lower of the IPPS comparable per diem amount under § 412.529(d)(4), including any applicable outlier payments under § 412.525(a), or 100 percent of the estimated cost of the case. Consistent with the requirements of section 1886(m)(6)(B)(ii) of the Act, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24531 through 24532), we proposed under new § 412.522(c)(1) that the site neutral payment rate is the lower of the IPPS comparable per diem amount determined under § 412.529(d)(4), including any applicable outlier payments under § 412.525(a), or 100 percent of the estimated cost of the case determined under § 412.529(d)(2).

Under our proposed calculation of the site neutral payment rate, new § 412.522(c)(1)(i) provides that the IPPS comparable per diem amount would be calculated using the same method used to determine an amount comparable to the hospital IPPS per diem amount as set forth in the existing regulations at§ 412.529(d)(4), consistent with section 1886(m)(6)(B)(ii)(I) of the Act. Specifically, in the RY 2007 LTCH PPS final rule (71 FR 27852 through 27853), we established a method to determine an amount payable under 42 CFR part 412, subpart O, that is comparable to what would otherwise be paid under the IPPS for the costs of inpatient operating services, which is commonly referred to as the ''the IPPS comparable per diem amount.'' Accordingly, consistent with § 412.529(d)(4), we proposed to determine the IPPS comparable per diem amount based on the standardized amount determined under § 412.64(c), adjusted by the applicable DRG weighting factors determined under § 412.60 as specified at § 412.64(g). We also proposed to further adjust this amount to account for differences in area wage levels based on geographic location using the applicable IPPS labor-related share and the IPPS wage index for nonreclassified hospitals published in the annual IPPS final rule in accordance with § 412.525(c). For LTCHs located in Alaska and Hawaii, we proposed that this amount would be further adjusted by the applicable COLA factors established annually during the rulemaking cycle. We also proposed that the IPPS comparable per diem amount include an adjustment for treating a disproportionate share of low-income patients, consistent with the DSH payment adjustment under § 412.106, as applicable, which would include a proxy adjustment for the uncompensated care payment (78 FR 50765 through 50767). In the case of an LTCH that is a teaching hospital, we proposed that the IPPS comparable per diem amount include an IME payment adjustment, consistent with the formula set forth under § 412.105, where the LTCH's IME cap (that is, the limit on the number of full-time equivalent (FTE) residents that may be counted for IME) would be imputed from the LTCH's direct GME cap as set forth at § 413.79(c)(2). In addition, we proposed that the IPPS comparable per diem amount also include payment for inpatient capital-related costs, based on the capital IPPS Federal rate determined in accordance with § 412.308(c), adjusted by the applicable IPPS DRG weighting factors. We proposed to further adjust the capital IPPS Federal rate by the applicable geographic adjustment factors based on the geographic location of the LTCH and the COLA factors for LTCHs located Alaska and Hawaii, consistent with § 412.316. In addition, we proposed to include in this amount the adjustments to the capital IPPS Federal rate for DSH payments in accordance with § 412.320 and IME payments in accordance with § 412.322. Consistent with

§§ 412.529(d)(4)(i)(B) and (C), we proposed to determine the IPPS comparable per diem amount by dividing the IPPS comparable payment amount described above by the geometric average length of stay of the specific MS–DRG under the IPPS and multiplying that amount by the covered days of the LTCH stay. We proposed that the IPPS comparable per diem amount is limited to the full comparable amount to what would otherwise be paid under the IPPS.

Comment: Several commenters expressed concern regarding CMS' proposal to establish that the new LTCH site neutral payment rate as the lesser of the IPPS comparable per diem amount, or 100 percent of the estimated cost of the case. Specifically, the commenters stated that an LTCH would receive a lower payment than an IPPS hospital for treating the same type of case. Therefore, the commenters recommended that CMS pay LTCH site neutral payment rate cases the exact amount that would be paid for the case under the IPPS.

Response: We acknowledge the commenters' concerns. However, section 1886(m)(6)(B)(ii) of the Act specifies that the site neutral payment rate is the lower of the IPPS comparable per diem amount under § 412.529(d)(4), including any applicable outlier payments under § 412.525(a), or 100 percent of the estimated cost of the case. Without the enactment of further legislation, we do not have the authority to make any further adjustments to the calculation of the site neutral payment rate that would guarantee that payment for such a case would equal the exact amount paid for an identical discharge from an IPPS hospital.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to establish that the site neutral payment rate is the lesser of the IPPS comparable per diem amount, or 100 percent of the estimated cost of the case.

The IPPS comparable per diem amount described under § 412.529(d)(4) does not include additional payments for extraordinarily high-cost cases under the IPPS outlier policy. Therefore, consistent with the requirements of section 1886(m)(6)(B)(ii)(I) of the Act, under our proposed calculation of the site neutral payment rate under new § 412.522(c)(1), we proposed to add any high-cost outlier (HCO) payment that may be payable under § 412.525(a) to the IPPS comparable per diem amount. To do so, we also proposed to revise the HCO policy under existing § 412.525(a) to provide for high-cost outlier payments under the site neutral payment rate calculated under proposed new § 412.522(c) (as discussed in greater detail in section VII.B.7.b. of the preamble of this final rule). We proposed that site neutral payment rate cases receive an additional payment for HCOs that would be equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which we are proposing would be the sum of site neutral payment rate for the case and the IPPS fixed-loss amount. We also proposed that HCO payments for site neutral payment rate cases would be budget neutral and proposed to apply a budget neutrality factor to the LTCH PPS payments for those cases to maintain budget neutrality. (For additional information on our revised HCO policy in regard to site neutral payment rate cases under § 412.525(a), we refer readers to section VII.B.7.b. of the preamble of this final rule.)

Comment: Commenters supported the proposal to under new § 412.522(c)(1) to include any applicable HCO payments specified in § 412.525(a) in the IPPS comparable per diem amount determined under § 412.529(d)(4) when determining the payment for site neutral payment rate cases. We also received comments on our proposed revisions to the HCO policy under existing § 412.525(a) to determine high-cost outlier payments under the site neutral payment rate, which are discussed in section VII.B.7.b. of the preamble of this final rule.

Response: We appreciate the commenters' support. We are adopting this proposal, without modification. As noted above, we refer readers to section VII.B.7.b. of the preamble of this final rule for a discussion of our revisions to the HCO policy under existing § 412.525(a) to determine high-cost outlier payments under the site neutral payment rate, and summations of the public comments we received, including our responses to those comments, and a statement of our final policy.

Furthermore, under our proposed calculation of the site neutral payment rate, under proposed new § 412.522(c)(1)(ii), we proposed to calculate 100 percent of the estimated cost of a case by multiplying the LTCH's hospital-specific cost-to-charge ratio (CCR) by the Medicare allowable charges for the LTCH case, which is the same method we use to determine SSO payments under § 412.529(d)(2), as well as HCO payments under the HCO policy under § 412.525(a). Consistent with our existing policies for computing CCRs under the LTCH PPS, we also proposed to apply the payment policies described under §§ 412.529(f)(4)(i) through (f)(4)(iii) to the calculation of the estimated cost of the case for site neutral payment rate cases under proposed new § 412.522(c)(1)(ii). Under this proposal, the CCR applied at the time a claim is processed would generally be based on either the most recent settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. CMS may specify an alternative to the CCR otherwise applicable if we believe that the CCR being applied is inaccurate, in accordance with section 150.24 of Chapter 3 of the Medicare Claims Processing Manual (Pub. 100–4), or an LTCH may request an alternate (higher or lower) CCR based on its presentation of substantial evidence in support of that alternate. The CMS Regional Office must approve the request, and the MAC notifies the LTCH whenever a change is made to its CCR. The applicable MAC may also use the statewide average CCR that is established annually by CMS if it is unable to determine an accurate CCR for an LTCH under one of the circumstances specified at existing § 412.529(f)(4)(iii) (that is, in general, for a new LTCH, when the LTCH's CCR exceeds 3 standard deviations from the corresponding national geometric mean CCR, and for an LTCH for which data to calculate a CCR are otherwise not available). These same CCR policies also are applicable under the LTCH PPS HCO policy (§§ 412.525(a)(4)(iv)(B) and (a)(4)(iv)(C)).

We did not receive any public comments on our proposal to calculate 100 percent of the estimated cost of a site neutral payment rate case by multiplying the LTCH's hospital-specific CCR by the Medicare allowable charges for the LTCH case, and to codify this policy under new § 412.522(c)(1)(ii). Therefore, we are adopting that proposal, without modification.

In the FY 2016 IPPS/LTCH PPS (80 FR 24532), we proposed to include a reconciliation adjustment to site neutral payment rate cases. Currently, under the LTCH PPS, payments for HCO and SSO cases may be subject to reconciliation at cost report settlement under § 412.525(a)(4)(iv)(D) and § 412.529(f)(4)(iv), respectively. Under these policies, reconciliation is based on the CCR calculated using the CCR computed from the settled cost report that coincides with the discharge. Under our existing criteria, reconciliation occurs in instances where an LTCH's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate payments when a

claim is processed. We adopted this reconciliation policy for the LTCH PPS HCO and SSO cases because CCRs based on settled cost reports are not available when claims are processed unless significant delays are imposed on the payment of claims. (For additional information, we refer readers to the June 9, 2003 IPPS/LTCH PPS high-cost outlier final rule (68 FR 34507) and sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4).) Given the use of LTCH CCRs to calculate the estimated cost of cases under the proposed site neutral payment rate, we stated in the proposed rule that we believe that it would be equally appropriate to apply the current CCR reconciliation policy principles to site neutral payment rate payments. Therefore, we proposed under new § 412.522(c)(4) to reconcile site neutral payment rate payments based on the CCR calculated using the settled cost report that coincides with the discharge. We also proposed that, at the time of any such reconciliation of site neutral payment rate payments, such payments be adjusted to account for the time value of any underpayments or overpayments. Any adjustment would be based upon a widely available index to be established in advance by the Secretary and will be applied from the midpoint of the cost reporting period to the date of reconciliation. The index that would be used to calculate the time value of money is the monthly rate of return that the Medicare Trust Fund earns, which can be found at: *http://www.ssa.gov/OACT/ProgData/newIssueRates.html*, consistent with our current reconciliation policy described in section 150.27 of Chapter 3 of the Medicare Claims Processing Manual (Pub. 100–4). Furthermore, we proposed that our existing policies governing CCRs for both HCO (under §§ 412.525(a)(4)(iv)(A) through (C)) and SSO payments (under §§ 412.529(f)(4)(i) through (iii)) would apply to the CCRs used to determine the estimated cost of a case under proposed new § 412.522(c)(4).

Comment: Several commenters disagreed with CMS' proposal to apply our existing reconciliation policy to payments made for site neutral payment rate cases. The commenters stated that such a policy is unprecedented and contrary to the predictability of a PPS. They believed that applying a reconciliation policy to payments for site neutral payment rate cases would result in an adjustment to all LTCH site neutral payment rate cases for every LTCH at the conclusion of every cost reporting period.

Response: We disagree with the commenters. Consistent with the current reconciliation policy, payments for site neutral payment rate cases would be subject to reconciliation only when certain criteria are met. As noted above and referenced by several commenters, the current criteria for reconciliation are presented in sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100 4), and include the criterion that the LTCH's actual CCR must be plus or minus 10 percentage points from the CCR used during that cost reporting period to trigger outlier payments. The purpose of the policy was not intended to automatically require that all payments for site neutral payment rate cases in every LTCH's cost reporting period be reconciled. Nevertheless, we understand the commenters' concerns regarding the need for predictability and stability in LTCH PPS payments. Therefore, we believe that it would be appropriate to generally postpone the implementation of a reconciliation policy for site neutral payments until we have gained more experience under the revised LTCH PPS. This approach would allow CMS the opportunity to review the existing reconciliation criteria, and revise, if appropriate, that criteria to identify the circumstances under which it would be appropriate to reconcile the entire site neutral payment rate payment amount, should it be determined that such a policy is warranted. However, we continue to believe that it is appropriate to include any HCO payments made to site neutral payment rate cases in our existing reconciliation policy. Such a policy provides for a consistent application of the reconciliation policy to both site neutral payment rate cases and LTCH PPS standard Federal payment rate cases, while we monitor whether it may be appropriate to apply a reconciliation policy to the entire site neutral payment rate as we gain experience under the revised LTCH PPS.

Therefore, we are not finalizing the proposal to apply, under new § 412.522(c)(4), a reconciliation policy to payments made for site neutral payment rate cases. However, we are finalizing the proposal to include any HCO payments made for site neutral payment rate cases under the existing reconciliation policy at § 412.525(a)(4)(iv)(D). (As noted previously, our HCO policy for site neutral payment rate cases is discussed in detail in section VII.B.7.b. of the preamble of this final rule.)

b. Blended Payment Rate for FY 2016 and FY 2017

Section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that will 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 to be the blended payment rate specified in section 1886(m)(6)(B)(iii) of the Act. For LTCH discharges occurring in cost reporting periods beginning during FY 2018 or later, the applicable site neutral payment rate will be the site neutral payment rate as defined in section 1886(m)(6)(B)(ii) of the Act.

Section 1886(m)(6)(B)(iii) of the Act specifies that the 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. As previously discussed, we proposed to codify the site neutral payment rate specified under section 1886(m)(6)(B)(ii) of the Act under proposed new § 412.522(c)(1), as adjusted under proposed new § 412.522(c)(2). Under proposed new § 412.522(c)(1), the site neutral payment rate is the lower of the IPPS comparable per diem amount determined under § 412.529(d)(4), including any applicable outlier payments under § 412.525(a), or 100 percent of the estimated cost of the case determined under § 412.529(d)(2). For purposes of the blended payment rate, we proposed that the payment rate that would otherwise be applicable if section 1886(m)(6) of the Act had not been enacted would be the LTCH PPS standard Federal payment; which, in light of other proposals presented in the proposed rule, would be the LTCH PPS standard Federal payment rate that is applicable to discharges that meet the criteria for exclusion from the site neutral payment rate under proposed new § 412.522(a)(2). That rate is the LTCH PPS standard Federal payment rate determined under § 412.523. Therefore, consistent with the requirements of section 1886(m)(6)(B)(ii) of the Act, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24533), we proposed under proposed new § 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 would be a blended payment rate, which would be calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under proposed new § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate determined under § 412.523. Under this proposal, the payment amounts determined under proposed new § 412.522(c)(1) (the site neutral payment rate) and under § 412.523 (the LTCH PPS standard Federal rate) would include any applicable adjustments, such as HCO payments, as applicable, consistent with the requirements under § 412.523(d). For example, the portion of the blended payment for the discharge that is based on proposed new § 412.522(c)(3) would include 50 percent of any applicable site neutral payment rate HCO payment under our revised HCO payment policy (discussed in detail in section VII.B.7.b. of the preamble of this final rule), consistent with proposed new § 412.522(c)(1)(i), which provides for HCO payments under § 412.525(a). Similarly, the portion of the blended payment for the discharge that is based on the LTCH PPS standard Federal payment rate would include any applicable HCO payment under existing § 412.525(a).

Comment: Some commenters requested that CMS establish a longer transitional period for LTCHs to receive blended payments because of the concern that reduced payments to LTCHs under the revised LTCH PPS would create a negative impact on these providers.

Response: We acknowledge the commenters' concerns. However, the blended payment rate provided under the statute is only applicable to LTCH discharges occurring during FY 2016 and FY 2017, and does not extend applicability to discharges occurring during cost reporting periods beginning in FY 2018 and subsequent fiscal years.

After consideration of the public comments we received, we are finalizing our proposed policy, without modification.

c. LTCH PPS Standard Federal Payment Rate

Section 1206(a) of Public Law 113–67 amended section 1886(m) of the Act by adding paragraph (6), which specifies that beginning with cost reporting periods starting on or after October 1, 2015, all LTCH PPS discharges are paid according to the site neutral payment rate, unless certain criteria are met. For detailed discussion of our proposed and finalized policies regarding the criteria for exclusion from the site neutral payment rate, we refer readers to section VII.B.3. of the preamble of this final rule. For LTCH cases that meet the criteria for exclusion from the site neutral payment rate, section 1886(m)(6)(A)(ii) of the Act specifies that the site neutral payment rate will not apply and payment will be made without regard to requirements of section 1886(m)(6)(A)(ii) of the Act. Consistent with these statutory requirements, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24533), we proposed under new § 412.522(a)(2) that for LTCH discharges that meet the criteria for exclusion from site neutral payment rate under new § 412.522(b), payment will be based on the LTCH PPS standard Federal payment rate as determined in § 412.523. That is, under new § 412.522(a)(2), LTCH PPS standard Federal payment rate cases would continue to be paid based on the LTCH PPS standard Federal payment rate. Under this policy, all of the existing payment adjustments under § 412.525(d), that is, the adjustments for SSO cases under § 412.529, the adjustments for interrupted stays under § 412.531, and the 25-percent threshold policy under § 412.534 and § 412.536, would still apply if appropriate. In addition, as discussed in greater detail in section VII.B.7.b. of the preamble of the proposed rule and this final rule, we proposed that our existing HCO policy would apply to LTCH PPS standard Federal payment rate cases, except that the 8 percent HCO target would be established using only data from LTCH PPS standard Federal payment rate cases.

We did not receive any public comments on our proposal to pay for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate under new § 412.522(a)(2) based on the LTCH PPS standard Federal payment rate. We are adopting this policy as final, without modification. We note that we proposed changes to the MS–LTC–DRG relative weight calculations and HCO policy for LTCH PPS standard Federal payment rate cases, which are discussed in in section VII.B.7. of the preamble of this final rule and include summations of the public comments we received and our responses.

5. Application of Certain Existing LTCH PPS Payment Adjustments to Payments Made Under the Site Neutral Payment Rate

Consistent with current LTCH PPS payment policies for adjusting Federal prospective payments, under the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24533 through 24534), we proposed that certain existing payment adjustments under the special payment provisions set forth at existing § 412.525(d), with the exception of the SSO adjustment described under § 412.525(d)(1) would apply to site neutral payment rate cases. These adjustments include the interrupted stay policy and the 25-percent threshold policy. The current payment adjustment under the interrupted stay policy at § 412.531 was developed and implemented prior to the statutory LTCH PPS dual rate payment structure and contains terms specific to payment based on the LTCH PPS standard Federal payment rate (such as LTC–DRG payment and Federal LTC–DRG prospective payment). Under our proposal, the site neutral payment rate would not be calculated based on the LTCH PPS standard Federal payment rate because the payment would generally be the lower of the IPPS comparable per diem amount (including any applicable outlier payments), or 100 percent of the estimated cost of the case. Consequently, in order to apply the provisions of the existing interrupted stay policy at § 412.531 to site neutral payment rate cases, under proposed new § 412.522(c)(2)(ii), we proposed to specify that, for purposes of the application of the provisions of § 412.531 to LTCH discharges described under § 412.522(a)(1), the LTCH PPS standard payment-related terms, such as ''LTC–DRG payment'', ''full Federal LTC–DRG prospective payment'', and ''Federal prospective payment,'' mean the site neutral payment rate calculated under proposed new § 412.522(c).

We stated in the proposed rule that we believe that it is appropriate to apply these adjustments to the site neutral payment rate cases because the site neutral payment rate merely establishes an alternate payment amount under the LTCH PPS, as opposed to creating an exception from the LTCH PPS. Additionally, we believe that the policy concerns upon which these policies are based apply equally to payments made under the LTCH PPS site neutral payment rates and the standard Federal payment rates.

We established the interrupted stay policy to address instances in which a patient is discharged from an LTCH and later readmitted to that LTCH within a certain amount of time. This kind of readmission to the LTCH represents a continuation or resumption of the initial, interrupted treatment, rather than a new episode of care. (For a

discussion of our implementation of the interrupted stay policy, we refer readers to the RY 2003 LTCH PPS final rule (67 FR 56002).) We continue to believe that the interrupted stay policy serves as an effective instrument to protect the Medicare Trust Fund from significant and inappropriate expenditures (78 FR 50768), and we do not believe that the site neutral payment rate will address these concerns unless the interrupted stay policy is applied to site neutral payment rate cases in the same manner as it is applied to standard Federal payment rate cases.

The 25-percent threshold payment adjustment policy was implemented based on analyses of Medicare discharge data that indicated that patterns of patient shifting appeared to be occurring more for provider financial advantage than for patient benefit. In order to discourage such activity, a payment adjustment was applied to LTCH discharges of patients who were admitted to the LTCH from the same referring hospital in excess of an applicable percentage threshold (79 FR 50185). We refer readers to the detailed discussions of the 25-percent threshold payment adjustment policy for LTCH hospital-within-hospitals (HwHs) and LTCH satellite facilities in the FY 2005 IPPS/LTCH final rule (69 FR 49191 through 49214) and its application to all other LTCHs in the RY 2008 LTCH PPS final rule (72 FR 26919 through 26944), as well as our discussion in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50185 through 50187), for additional details on the 25-percent threshold payment adjustment. We do not believe that the site neutral payment rate will address these patient shifting concerns unless the 25-percent threshold payment adjustment is applied to site neutral payment rate cases in the same manner as it is applied to LTCH PPS standard Federal payment rate cases.

In considering the potential policy proposals, we recognized that there is a current statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy under section 1206(b)(1)(A) of Public Law 113–67 that is scheduled to expire in FY 2016. (For a discussion of our implementation of the current statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50185 through 50187).) In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24533 through 24534), we proposed to apply all of the payment adjustments to site neutral payment rates in the same manner as they are currently applied (and will continue to be applied for the foreseeable future) to LTCH PPS standard Federal payment rates—including, as applicable, the moratorium on implementing the 25-percent threshold payment adjustment.

We did not propose to apply the SSO payment adjustment to the site neutral payment rate at this time because, while the policy goal of ensuring patients in an LTCH receive a full course of treatment remains, under our current method of paying for SSOs as described under § 412.529, we pay for SSOs based on the lowest of several payment options, one of which is the LTCH's estimated cost of the case. As described above, site neutral payment rate cases are paid the lower of the IPPS comparable per diem amount, or 100 percent of the estimated cost of the case. Because the estimated cost option is used in determining both SSO payments and site neutral payment rates and both methods make payment based on the lowest of their respective payment options, in most cases, applying our current SSO payment adjustment to site neutral payment rate cases would not affect the resulting LTCH PPS payment made for the discharge. We may consider proposing the application of an alternative SSO payment adjustment in the future if we find evidence that Medicare beneficiaries are not regularly receiving the full course of treatment when such treatment is paid for at the site neutral payment rate.

Comment: MedPAC supported the CMS proposal to apply the interrupted stay policy and the 25-percent threshold policy to site neutral payment rate cases. However, other commenters disagreed with the proposal and indicated that one or both of these policies should be eliminated entirely because the concerns that led to these policies are addressed with the statutory revisions to the payment rates under the LTCH PPS. The commenters stated that if the policies are not eliminated entirely that, at a minimum, the provisions should not apply to site neutral payment rate cases because payments for site neutral payment rate cases are similar to the payments under the IPPS for these types of cases, and the lengths of stay for site neutral payment rate cases should be similar to the lengths of stay for similar cases paid under the IPPS. Some commenters suggested that CMS establish an IRF-like interrupted stay policy as an alternative to the LTCH interrupted stay policy. Some commenters noted that CMS indicated in prior rulemakings that the revised LTCH PPS would render the 25-percent threshold policy unnecessary. Other commenters suggested that CMS apply the 25-percent threshold policy to site neutral payment rate cases prior to applying the policy to LTCH PPS standard Federal payment rate cases as an alternative to excluding site neutral payment rate cases from the 25-percent threshold policy altogether.

Response: We appreciate MedPAC's support. In response to the commenters who disagreed with the proposals, we believe that it is premature to determine if modifications should be made to these polices, including their applicability to site neutral payment rate cases, without the benefit of experience gained under the revised LTCH PPS; especially given that the higher blended payment rate will apply to LTCH discharges that do not meet the criteria for exclusion from the site neutral payment rate until cost reporting periods beginning on or after October 1, 2017. In addition, we did not indicate in prior rulemakings that these policies were unnecessary. We stated that, at that time, the policies may no longer be necessary in light of the intended changes to the LTCH PPS. We believe that it would be prudent to maintain these policies as they currently exist, including their applicability to site neutral payment rate cases, while we gain more experience. However, we will keep this suggestion in mind when contemplating whether the current policy should be modified. In the event that we determine that policy modifications are warranted, we will address them through future rulemaking.

Comment: One commenter requested clarification about our proposed application of the 25-percent threshold policy to site neutral payment rate cases.

Response: The 25-percent threshold policy would apply to site neutral payment rate cases in the same manner as it would apply to LTCH PPS standard Federal payment cases; all LTCH discharges (site neutral payment rate cases or LTCH PPS standard Federal payment rate cases) that are beyond an LTCH's applicable threshold from a single referring hospital would be subjected to an adjustment in accordance with the 25-percent threshold policy.

Comment: Several commenters expressed support for our proposal not to apply the SSO policy to site neutral payment rate cases. Other commenters believed that the SSO policy should be modified in consideration of site neutral payment rate cases.

Response: We appreciate the commenters' support. We will consider the commenters' suggestions to revise the SSO policy, and may consider additional policy proposals to address this issue in future rulemaking.

After consideration of public comments we received, we are finalizing, without modification, our proposals to apply the interrupted stay policy and the 25-percent threshold policy to site neutral payment rate cases, and not to apply the SSO policy to site neutral payment rate cases at this time.

6. Policies Relating to the LTCH Discharge Payment Percentage

Section 1886(m)(6)(C) of the Act, as added by section 1206 of Public Law 113–67, imposes several requirements related to an LTCH's discharge payment percentage. As defined by section 1886(m)(6)(C)(iv) of the Act, the term ''LTCH discharge payment percentage'' is a ratio, expressed as a percentage, of Medicare discharges not paid the site neutral payment rate to total number of Medicare discharges occurring during the cost reporting period. In other words, an LTCH's discharge payment percentage would be the ratio of an LTCH's Medicare discharges that meet the criteria for exclusion from the site neutral payment rate (as described under new § 412.522(a)(2)) to an LTCH's total number of Medicare discharges paid under the LTCH PPS (that is, both Medicare discharges paid under the site neutral payment rate and those that meet the criteria for exclusion from the site neutral payment rate, as described under new §§ 412.522(a)(1) and (2), respectively) during the cost reporting period. Therefore, consistent with the statutory requirement at section 1886(m)(6)(C)(iv) of the Act and under the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24534) under proposed new § 412.522(d)(1), we proposed to define an LTCH's discharge payment percentage as a ratio, expressed as a percentage, of Medicare discharges excluded from the site neutral payment rate as described under proposed new § 412.522(a)(2) to total Medicare discharges paid under the LTCH PPS (in accordance with 42 CFR part 412, subpart O) during the cost reporting period.

Comment: One commenter requested clarification about whether our proposed definition of the discharge payment percentage included Medicare Advantage beneficiaries, and noted that the statute expressly excludes these beneficiaries from the percentage.

Response: We agree with the commenter that the exclusion of Medicare Advantage beneficiaries is consistent with the statute. We believe that our proposed use of the phrase ''Medicare discharges paid under the LTCH PPS (in accordance with 42 CFR part 412, subpart O)'' was a clear statement concerning the exclusion of Medicare Advantage beneficiaries from the discharge patient percentage (80 FR 24534). However in the interest of clarity, we are taking this opportunity to reiterate that the LTCH's discharge payment percentage under new § 412.522(d)(1) would not include Medicare Advantage patients in either the numerator or denominator of that ratio.

Comment: One commenter requested we develop a procedure by which LTCHs who demonstrate ''highly compliant'' discharge payment percentages would receive payment for all discharges at the LTCH PPS standard Federal payment rate.

Response: As explained more fully previously in this preamble, we do not have the authority to pay any rate other than the site neutral payment rate for discharges that do not meet the exclusion statutory criteria.

After consideration of the public comments we received, we are finalizing our proposed definition of the discharge patient percentage under new § 412.522(d)(1), including the technical correction of the typographical error in the phrase ''paid under this Subpart O'' that we are correcting to read as ''paid under this subpart'' for clarity.

In addition, section 1886(m)(6)(C)(i) of the Act requires that we provide notice to each LTCH of the LTCH's discharge payment percentage (as defined in section 1886(m)(6)(C)(iv) of the Act) for LTCH cost reporting periods beginning during or after FY 2016. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24534 through 24535), we proposed to codify this statutory requirement at proposed new § 412.522(d)(2). Under this proposal, for cost reporting periods beginning on or after October 1, 2015, as required by the statute, we would inform each LTCH of their discharge payment percentage as defined under proposed new § 412.522(d)(1). We stated that we plan to develop such a notification process through subregulatory guidance. We also note that, under section 1886(m)(6)(C)(ii) of the Act, for cost reporting periods beginning on or after October 1, 2020, the statute requires that any LTCH whose discharge payment percentage for the period is not at least 50 percent will be informed of such a fact and all of the LTCH's discharges in each successive cost reporting period will be paid the payment amount that would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital, subject to the process for reinstatement provided for by section 1886(m)(6)(C)(iii) of the Act.

Because this statutory requirement is not effective until cost reporting periods beginning on or after October 1, 2020, we did not propose to make any changes related to the limitation requirement or the process for reinstatement at this time. However, we invited public comments on the development and implementation of the process for reinstatement under section 1886(m)(6)(C)(iii) of the Act.

Comment: Several commenters requested that CMS develop internal procedures and instructional mechanisms that explain how LTCHs will be notified of their discharge patient percentage through rulemaking.

Response: We appreciate the commenters' input regarding the limitation requirements or the process for reinstatement as a result of the discharge patient percentage policy, including suggestions for ''cure periods'' for LTCHs whose discharge patient percentages fall below 50 percent. We will consider these comments as we develop proposals in these areas for discharges occurring in cost reporting periods beginning on or after October 1, 2020. However, we note that the development of operational guidance consistent with the law and our regulations does not require rulemaking. We will continue to engage with stakeholders as we develop operational guidance for our contractors.

After consideration of the public comments we received, we are finalizing, without modification, our proposals to codify the statutory requirement under new § 412.522(d)(2) that we provide notice to each LTCH of its discharge payment percentage for each cost reporting period beginning on or after October 1, 2015.

7. Additional LTCH PPS Policies Related to the Implementation of the Site Neutral Payment Rate Required by Section 1206(a) of Public Law 113–67

As discussed earlier in this section, section 1206(a) of Public Law 113–67 amended section 1886(m) of the Act by adding paragraph (6), which establishes patient-level criteria for payments made under the LTCH PPS for LTCH discharges occurring during cost reporting periods beginning on or after October 1, 2015 (FY 2016). In the FY 2015 IPPS/LTCH PPS proposed and final rules, we stated our intent to implement the requirements established by section 1206(a) of Public Law 113–67 through notice and comment rulemaking during the FY 2016 IPPS/LTCH PPS rulemaking cycle. In the FY

2015 IPPS/LTCH PPS proposed rule (79 FR 28205 through 28206), we discussed several significant issues arising from the statutory changes to the LTCH PPS required by section 1206(a) of Public Law 113–67, which establishes two distinct payment groups for LTCH discharges under the revised system: Discharges meeting specified patient-level criteria that will be paid under the LTCH PPS standard Federal payment rate and all other patient discharges that will be paid under the site neutral payment rate. In that same proposed rule, we expressed our interest in receiving feedback from LTCH stakeholders on our plans to evaluate whether it would be appropriate to modify any of our historical policies or methodologies as we began to develop proposals to implement the statutory changes to the LTCH PPS. In particular, we solicited public feedback on the policies relating to the MS–LTC–DRG relative payment weights and high-cost outlier payments in preparation of developing proposals to implement the statutory changes to the LTCH PPS beginning in FY 2016. We explained that in setting the payment rates and factors under the LTCH PPS in accordance with requirements of section 1206(a) of Public Law 113–67, for certain LTCH PPS payment adjustments we planned to evaluate whether it would be appropriate to modify our historical methodology to account for the establishment of the two distinct payment rates for LTCH discharges. In particular, we stated our intent to examine whether, beginning in FY 2016, it would continue to be appropriate to include data for all LTCH PPS cases, including site neutral payment rate cases, in the methodology used to set the MS–LTC–DRGs relative payment weights. We also stated our intent to explore the possibility of changes to the current LTCH PPS high-cost outlier payment policy. Given the fact that, for a number of LTCH discharges, payment would be made based on the lower site neutral payment rate (that is, the lesser of an ''IPPS comparable'' per diem payment amount or 100 percent of the estimated cost of the case), we believed that it would be appropriate to evaluate whether a single high-cost outlier threshold could be applied to all LTCH PPS cases (both LTCH PPS standard Federal payment rate and site neutral payment rate cases), or whether it may be more appropriate to have separate high-cost outlier thresholds for each of the two payment rates under the statutory revisions to the LTCH PPS.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50197 through 50198), we summarized the comments we received in response to our request for input from LTCH stakeholders. As we stated in that same final rule, we appreciated the commenters' thoughtful and detailed feedback, particularly those comments regarding the MS–LTC–DRG relative payment weights and the high-cost outlier policy under the new LTCH PPS dual rate payment structure established by section 1206(a) of Public Law 113–67. In developing the proposals presented in the FY 2016 IPPS/LTCH PPS proposed rule, we considered the recommendations and information provided by those commenters. Below we discuss our proposed and finalized policies related to the MS–LTC–DRG payment relative weights and high-cost outlier policy in regard to our implementation policies under the LTCH PPS dual rate payment structure required by section 1206(a) of Public Law 113–67.

a. MS–LTC–DRG Relative Payment Weights

Under the LTCH PPS, relative payment weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization between the diagnosis-related groups (§ 412.515). Each year, based on the latest available LTCH claims data, we calculate a relative payment weight for each MS–LTC–DRG that represents the resources used for an average inpatient LTCH case assigned to that MS–LTC–DRG to ensure that Medicare patients with conditions or illnesses classified under each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency (79 FR 50170). CMS adjusts the classifications and weighting factors annually to reflect changes in factors affecting the relative use of hospital resources, such as treatment patterns, technology, and the number of discharges (§ 412.517).

Under the new dual rate LTCH PPS payment structure, section 1206(a) of Public Law 113–67 establishes two distinct payment rates for LTCH discharges: discharges meeting specified patient-level criteria that will be excluded from the site neutral payment rate and all other patient discharges that will be paid under the site neutral payment rate. As discussed in greater detail in section VII.B.4.c. of the preamble of our proposed rule and this final rule, under new § 412.522(a)(2), we are establishing that LTCH discharges that meet the criteria for exclusion from site neutral payment rate will be paid using the LTCH PPS standard Federal payment rate described under § 412.523, as adjusted. In general, the LTCH PPS standard Federal payment rate is calculated by adjusting the standard Federal rate (determined under § 412.523(c)(3)) by the applicable MS–LTC–DRG relative payment weight for that Medicare cases. Under new § 412.522(c) (as discussed in greater detail in section VII.B.4.a. of the preamble of this final rule), consistent with section 1886(m)(6)((B)(ii) of the Act, we are establishing that the site neutral payment rate is the lower of the IPPS comparable per diem amount (including any applicable outlier payments), or 100 percent of the estimated cost of the case. Under this policy, the IPPS comparable per diem amount is determined using the same method to determine adjusted payments under the SSO policy at § 412.529(d)(4), and the estimated cost of the case is determined using the same method to determine estimated costs under the SSO policy at § 412.529(d)(2). We also note that the methodology we are adopting to determine payments for site neutral payment rate cases does not use the LTCH PPS standard Federal payment rate or the applicable MS–LTC–DRG relative payment weights.

As discussed above, in preparation for the proposed rule, we considered LTCH stakeholder input and evaluated whether it would be appropriate to modify our historical MS–LTC–DRG relative payment weight methodology to account for the establishment of the two distinct payment rates for LTCH discharges under the statutory changes to the LTCH PPS. Specifically, we examined whether our historical methodology, which uses data from all LTCH PPS discharges, should be continued when we calculate the MS–LTC–DRG relative payment weights under the new LTCH PPS dual rate payment structure, or whether it would be more appropriate to limit the data used to calculate relative payment weights to that obtained from discharges paid based on the LTCH PPS standard Federal payment rate (that is, discharges that would have met the criteria to be excluded from the site neutral payment rate had those criteria been in effect at the time of the discharge). Our existing methodology for developing the MS–LTC–DRG relative payment weights includes established policies related to the data used to calculate the relative payment weights, the hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, the low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, and the calculation of the MS–LTC–DRG relative payment weights with a budget neutrality factor

(79 FR 50171). Our most recent discussion of the existing methodology for calculating the MS–LTC–DRG relative payment weights can be found in the FY 2015 IPPS/LTCH final rule (79 FR 50168 through 50176). For FY 2016, our finalized methodology for calculating the FY 2016 MS–LTC–DRG relative payment weights (including the policy we are finalizing below to use only data from cases that would have been LTCH PPS standard Federal payment rate cases had the new LTCH PPS payment structure been in effect at the time of the discharge) is discussed in section VII.C.3. of the preamble of this final rule.

In response to our solicitation for stakeholder input during the FY 2015 rulemaking cycle, we received numerous comments that addressed the calculation of the MS–LTC–DRG relative payment weights under the new statutory LTCH PPS structure. In its comment, MedPAC urged CMS to establish '' . . . new relative payment weights for each MS–LTC–DRG based solely on the most recent available standardized data associated with discharges meeting the specified patient-level criteria'' because those discharges under the new law would represent cases treating the most severely ill, incurring higher resource costs that warrant higher LTCH payments. MedPAC also stated that the change in methodology should not result in increased aggregate payments for the cases paid under the LTCH PPS standard Federal payment rate under the new statutory LTCH PPS structure. Most of the other commenters agreed with MedPAC's recommendation that the MS–LTC–DRG relative payment weights under the new statutory structure should be calculated using only the data from cases that meet the statutory patient-level criteria for exclusion from the site neutral payment rate (or cases that would have qualified for exclusion had the new LTCH PPS payment structure been in effect at the time of discharge) A few commenters conducted their own analyses and found that both relative payment weight approaches (that is, using data from all LTCH PPS cases as compared to using only data from standard Federal payment rate cases) produce MS–LTC–DRG relative payment weights that are similar. In addition, some of the commenters urged CMS to focus on keeping payments for LTCH PPS standard Federal payment rate cases at the same level that would have been in the absence of the statutory changes, or otherwise consider employing a methodology that promotes stability and predictability in the MS–LTC–DRG relative payment weights. Therefore, the overwhelming majority of the preliminary stakeholder feedback we received did not support using data from all LTCH PPS cases to determine the MS–LTC–DRG relative payment weights for the LTCH PPS standard Federal payment rate cases (80 FR 24536).

In the FY 2016 IPPS/LTCH PPS proposed rule, we expressed our appreciation for the commenters' detailed feedback and took into consideration their concerns and recommendations in our evaluation the issue of the MS–LTC–DRG relative payment weights under the new LTCH PPS structure required by section 1206(a) of Public Law 113–67 in preparation for that proposed rule. As part of our evaluation, as we discussed in the proposed rule (80 FR 24536), we examined the FY 2013 LTCH claims data used to determine the FY 2015 MS–LTC–DRG relative weights and found that approximately 54 percent of LTCH cases would meet the criteria for exclusion from the site neutral payment rate (that is, those cases would be paid the LTCH PPS standard Federal payment rate had the new criteria been in effect at the time of the discharge) and approximately 46 percent of LTCH cases would be paid the site neutral payment rate (had the new criteria been in effect at the time of the discharge). We then compared the MS–LTC–DRG relative payment weights computed using data from all LTCH PPS cases to the MS–LTC–DRG relative payment weights computed using only data from the LTCH PPS standard Federal payment rate cases (had those criteria been in effect at the time of the discharge). Specifically, using the FY 2013 LTCH claims data (the same LTCH claims data used in the FY 2015 IPPS/LTCH PPS final rule), we calculated FY 2015 MS–LTC–DRG relative payment weights using only data from the 54 percent of LTCH PPS cases that would be paid the LTCH PPS standard Federal payment rate, and compared them to the FY 2015 MS–LTC–DRG relative payment weights established in Table 11 of the FY 2015 IPPS/LTCH PPS final rule, which were calculated using data from all LTCH cases (that is, both case that would have been LTCH PPS standard Federal payment rate cases and would have been site neutral payment rate cases had those criteria been in place at the time of the discharge). Similar to results found by industry stakeholders, we found that both approaches produced comparable MS–LTC–DRG payments for LTCH PPS standard Federal payment rate cases. For example, our analysis of the average MS–LTC–DRG relative payment weight (that is, the case-mix) of LTCH PPS cases that would be paid the LTCH PPS standard Federal payment rate showed that the average case-mix using relative payment weights determined from using only data from LTCH PPS standard Federal payment rate cases differed by only approximately 0.01 percentage point from the average case-mix of those same cases using relative weights determined from data from all LTCH PPS cases.

However, we also discussed our belief that the costs and resource use for cases paid at the site neutral payment rate in the future may be lower on average than the costs and resource use for LTCH cases in our historical data that would have been paid at the site neutral payment rate if the statutory changes were in place when the discharges occurred. We believe that this is likely, even if the proportion of site neutral payment rate cases in future data remains similar to the historical data (that is, 46 percent). (We discuss our assumptions about cases paid at the site neutral payment rate in the future in more detail in section VII.B.7.b. of the preamble of this final rule, where we present our proposed and final policies regarding outlier payments for site neutral payment rate cases.) Therefore, even though the analysis described shows that including or excluding what would have been site neutral payment rate cases if the new statutory requirements were applied to the historical discharges would not have much impact on the relative payment weight calculation for FY 2016, over time we believe that the relative payment weights could become distorted if future site neutral payment rate cases involve less intensive resource use and lower costs, which we believe is a plausible response to the lower site neutral payment rates under the statutory LTCH PPS changes. This also could lead to less stability in the MS–LTC–DRG relative payment weights because these cases become incorporated into data used to calculate the relative payment weights.

Taking all of this information into account and given the feedback we received on this issue in the FY 2015 rulemaking cycle, we believe that computing the MS–LTC–DRG relative payment weights using only data from LTCH PPS cases that will be (or, in the future, are) paid the LTCH PPS standard Federal payment rate (that is, cases that meet the criteria for exclusion from the site neutral payment rate) will result in the most appropriate payments under

the new statutory structure. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24537), we proposed that, beginning with FY 2016, the annual recalibration of the MS–LTC–DRG relative payment weighting factors would be determined using only data from LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases). Accordingly, we proposed to codify this proposal by adding paragraph (c) to § 412.517 to specify that, beginning in FY 2016, the annual recalibration of the MS–LTC–DRG relative weighting factors are determined using data from LTCH discharges described under new § 412.522(a)(2), or that would have been described by that section had the new dual rate LTCH PPS payment structure been in effect at the time of discharge.

In addition, we proposed to continue to apply the existing budget neutrality requirement for the annual changes to the MS–LTC–DRG classifications and relative payment weights at § 412.517(b), which specifies that any such changes must be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected. We explained that we believe that a budget neutrality requirement is appropriate for the MS–LTC–DRG relative payment weights that would be used to determine LTCH PPS payments for LTCH PPS standard Federal payment rate cases for the same reasons discussed when the policy was originally adopted in the FY 2008 LTCH PPS final rule (72 FR 26880 through 26884). Therefore, we did not propose to make any changes to the budget neutrality requirement at § 412.517(b).

Comment: Several commenters, including the MedPAC, supported CMS' proposal, in general, to compute the MS–LTC–DRG relative payment weights using only data from LTCH PPS cases that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases). The commenters stated that this policy would result in appropriate LTCH PPS standard Federal payment rate payments under the new dual rate LTCH PPS because the discharges meeting the LTCH PPS standard Federal payment rate criteria are ''considered under the law to warrant the LTCH higher payments.'' Some of these commenters supported adopting this approach beginning in FY 2016, to correspond with the commencement of the new dual rate LTCH PPS payment structure. However, other commenters believed that, for FY 2016, the calculation of MS–LTC–DRG weights should be based on all LTCH cases in the available data, and then in subsequent years, the MS–LTC–DRG weights should be based on only LTCH cases meeting the new LTCH PPS standard Federal payment rate criteria. These commenters asserted that CMS' proposal was based upon the incorrect assumption that all LTCH discharges are immediately subject to the new dual rate LTCH PPS payment system after October 1, 2015, rather than LTCH discharges becoming subject to the new dual rate LTCH PPS payment structure based on the LTCH's cost reporting periods beginning on or after October 1, 2015. The commenters believed that because some LTCH discharges will be subject to the new dual rate LTCH PPS payment structure after October 1, 2015, CMS should set payment weights for those discharges using all LTCH claims in the available data because there should be no difference in the MS–LTC–DRG weighting methodology for the LTCH discharges that will not be subject to the new dual rate LTCH PPS payment structure until after October 1, 2015 (that is, LTCH discharges in cost reporting periods beginning before October 1, 2015). Some of these commenters requested that CMS establish two sets of MS–LTC–DRG relative weights for FY 2016—one set of relative weights computed using only data from LTCH PPS cases that would meet the criteria for exclusion from the site neutral payment rate as CMS proposed, which would apply to discharges in LTCH cost reporting periods that begin on or after October 1, 2015, and a second set of weights computed using all LTCH cases, regardless of whether they would meet the new patient criteria, which would apply to discharges in LTCH cost reporting periods that begin before October 1, 2015. Some commenters acknowledged the result of CMS' analyses included in the proposed rule that indicate that the MS–LTC–DRG relative weights overall are similar when using all LTCH cases or only those that meet the new criteria. However, these commenters stated that there could be notable variation for specific MS- LTC–DRGs. In addition, several commenters recommended that CMS explore options for improving the year-to-year stability of the MS–LTC–DRG weights and reducing any year-to-year variation that could result from smaller sample sizes, as they recommended previously when providing feedback during the FY 2015 rulemaking cycle.

Some commenters agreed with CMS' proposal to continue to make the annual changes to the MS–LTC–DRG classifications and relative payment weights in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected. One commenter believed that the budget neutrality requirement should not be included until the new payment system is in place, consistent the original implementation of the budget neutrality requirement, which was introduced a few years after the initial implementation of the LTCH PPS.

Response: We appreciate the commenters' support. However, we believe that the commenters are mistaken that, under this proposal, we did not consider the statutory phase-in and that we assumed that all LTCH discharges are immediately subject to the new dual rate payment structure after October 1, 2015. As explained in the proposed rule and reiterated above, we believe that this policy would result in appropriate LTCH PPS standard Federal payment rate payments under the new dual rate LTCH PPS, which becomes effective beginning on October 1, 2015. We also believe that this approach will promote stability and predictability in the MS–LTC–DRG relative weights under the revised LTCH PPS, which was a statement made by many commenters in the feedback they provided during the FY 2015 rulemaking cycle.

Furthermore, using only data from LTCH PPS cases that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) to compute the MS–LTC–DRG relative payment weights for FY 2016 is consistent with the HCO policy calculations we are finalizing in this final rule after consideration of public comments, which are discussed in section VII.B.7.b. of the preamble of this final rule. While we appreciate the commenters' recognition that using all of the cases in the historical data or only using cases that would have met the criterial for exclusion for the site neutral payment rate (had those criteria been in effect at the time of the discharge) would not have substantial impact on the relative weight calculation for FY 2016, we are aware that variation for specific MS–LTC–DRGs would occur as noted by commenters. However, such a variation can occur with the annual update of the relative weights based on the latest available LTCH PPS data under existing § 412.517, and, in general, appropriately adjusts the relative weights to reflect the resource use of LTCHs based on the best available data. For these reasons, we are not adopting the commenters' suggestions to calculate the FY 2016

MS–LTC–DRG relative weights based on all of the cases in the historical data or to calculate two sets of relative weights for FY 2016. As suggested by commenters, we intend to monitor the year-to-year changes in the MS–LTC–DRG relative weights, and to the extent issues such as stability or inappropriate variation are encountered, we would explore possible options to address those issues once we have more experience under the changes to the LTCH PPS.

We appreciate the comments we received in support of our proposal to continue to make the annual changes to the MS LTC DRG classifications and relative payment weights in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected. In addition to resulting in appropriate payments, we believe that this adjustment will continue to help to provide stability in LTCH PPS payments that are computed using the MS–LTC–DRG weights because the purpose of the budget neutrality adjustment is to ensure that estimated aggregate LTCH PPS payments do not increase or decrease as a result of the annual update of the MS–LTC–DRG classifications and relative weights. We do not believe that this change in Medicare payments to LTCHs is parallel to the change in Medicare payments to LTCHs under the initial implementation of the LTCH PPS in a way that would make it necessary to delay the continued application of the MS–LTC–DRG budget neutrality requirement. The period under which there was no MS–LTC–DRG budget neutrality requirement allowed LTCHs to adjust to a complete change in the structure of Medicare reimbursement; that is, from reasonable cost-based payments to a DRG-based prospective payment system, in which one of the primary elements for the basis of payments the coding of the diagnosis and procedure codes that are used to determine DRG assignment. As we explained when the policy was originally adopted, there had been fluctuations in the MS–LTC–DRG relative weights during the first 4 years of the LTCH PPS that were, in part, due to actual improvements in coding so that cases are appropriately assigned to MS–LTC–DRGs. We believed it was appropriate to establish the MS–LTC–DRG budget neutrality adjustment in the 5th year of the LTCH PPS when our annual case-mix index analysis indicated that changes in LTCH coding practices, which we believe were a primary contributor to in fluctuations in the MS–LTC–DRG relative weights in the past, had appeared to be stabilizing as LTCHs became more familiar with a DRG-based system (72 FR 26880). While the new dual rate LTCH PPS payment structure is arguably the most extensive change since the implementation of the LTCH PPS, it is not a complete change in the structure of Medicare payments to LTCHs, as was the case when LTCHs moved from cost-based payments to prospective payments. Therefore, we disagree with the commenter that it would be appropriate to delay the application of the MS–LTC–DRG budget neutrality requirement until LTCHs gain experience under the revised LTCH PPS.

After consideration of public commenters we received, for the reasons discussed above, we are finalizing, without modification, our proposal to compute the MS–LTC–DRG relative payment weights using only data from LTCH PPS cases that met the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases), or that would have met the criteria had the new dual rate LTCH PPS payment structure been in effect at the time of discharge, and to continue to apply the existing budget neutrality requirement for the annual changes to the MS–LTC–DRG classifications and relative payment weights. Furthermore, we are clarifying the language we proposed to codify this policy under new paragraph (c) of § 412.517, to specify that beginning in FY 2016, the annual recalibration of the MS–LTC–DRG relative weights is determined using LTCH PPS discharges described in § 412.522(a)(2) (or that would have been described in such section had the application of site neutral payment rate been in effect at the time of the discharge).

b. High-Cost Outliers

Under the LTCH PPS, the existing regulations at § 412.525(a) provide for an additional adjustment to LTCH PPS payments to account for outlier cases that have extraordinarily high costs relative to the costs of most discharges (referred to as high-cost outliers (HCOs).) Providing such adjustments for HCOs strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. In addition, HCO payments reduce the financial losses that would otherwise be incurred by hospitals when treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. Currently, we set the HCO threshold before the beginning of the payment year so that total estimated HCO payments are projected to equal 8 percent of estimated total payments under the LTCH PPS. Under our current HCO policy, an LTCH would receive an additional payment if the estimated cost of a case exceeds the adjusted LTCH PPS payment plus a fixed-loss amount. In such cases, the additional HCO payment amount is equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which is the sum of the adjusted Federal MS–LTC–DRG prospective payment amount for the case and the fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that an LTCH would incur under the HCO policy for a case with unusually high costs. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. Under the HCO policy, the fixed-loss amount is the maximum loss that an LTCH can incur for a case with unusually high costs before receiving an additional payment amount. The additional payment amount under the LTCH PPS HCO policy is determined using a marginal cost factor, which is a fixed percentage of costs above the HCO threshold. The marginal cost factor under the LTCH PPS HCO policy is 80 percent.

Under the current HCO policy, we annually determine a fixed-loss amount, that is, the maximum loss that an LTCH can incur under the LTCH PPS for a case with unusually high costs before an adjustment is made to the payment for the case. We do so by using the best available data to estimate aggregate LTCH PPS payments with and without a HCO policy, and, based on those estimates, set the fixed-loss amount at an amount that result in estimated total HCO payments being equal to 8 percent of estimated total LTCH PPS payments. Additional information on the LTCH PPS HCO methodology can be found in the FY 2003 LTCH PPS final rule (67 FR 56022 through 56027) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50398 through 50400).

As discussed in the previous section, under the new statutory LTCH PPS structure, section 1206(a) of Public Law 113–67 establishes two distinct payment rates for LTCH discharges beginning in FY 2016. To implement this statutory change, in the FY 2016 IPPS/LTCH PPS proposed rule, under proposed new § 412.522(a)(2), we proposed to pay for LTCH discharges that meet the criteria for exclusion from site neutral payment rate based on the LTCH PPS standard Federal payment rate, which includes HCO payments. Under proposed new § 412.522(c), consistent with the statute, we proposed that the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under existing

§ 412.529(d)(4) (including any applicable adjustments, such as outlier payments), or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). Below we discuss our proposed and finalized policies for determining HCO payments under the new statutory LTCH PPS payment structure.

In response to our solicitation for stakeholder input included in the FY 2015 IPPS/LTCH PPS proposed rule, we received numerous comments that addressed the HCO policy under the new statutory LTCH PPS structure. In its comment, MedPAC recommended that both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases receive HCO payments, and that estimated total HCO payments under the LTCH PPS continue to be projected to be equal to 8 percent of estimated total LTCH PPS payments for all cases (that is, both the LTCH PPS standard Federal payment rate cases and the site neutral payment rate cases). In contrast, most of the other commenters recommended that separate HCO fixed-loss amounts and separate HCO payment ''targets'' (that is, the projected percentage that estimated HCO payments are of estimated total payments) be determined for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases. Specifically, these commenters recommended that we calculate a fixed-loss amount under the current HCO policy for LTCH PPS standard Federal payment rate cases using only data (and estimated payments) from what would have been or are LTCH PPS standard Federal payment rate cases, without including data (and estimated payments) from cases that would have been or are paid the site neutral payment rate. In addition, some of the commenters recommended initially applying the existing HCO policy separately to both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases; that is, determining separate HCO fixed-loss amounts so that estimated HCO payments would be equal to 8 percent of estimated total payments for each of the two LTCH PPS payment types (the LTCH PPS standard Federal payment rate cases and site neutral payment rate cases), respectively, and then adjusting the HCO targets as more data under the statutory revisions to the LTCH PPS become available. In other words, commenters suggested that it may be more appropriate to have different HCO targets for the two LTCH PPS payment types rather than two HCO targets of 8 percent. When making recommendations regarding the HCO policy under the statutory LTCH PPS changes, several commenters urged CMS to focus on maintaining LTCH PPS payments for LTCH PPS standard Federal payment rate cases at the same payment level as they are currently under the LTCH PPS, including the level of HCO payments, and to mitigate any instability in the HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases.

Several commenters conducted independent analyses that looked at separate HCO fixed-loss amounts for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases. Upon review of their analyses, these commenters specifically recommended that separate HCO fixed-loss amounts be used for the two LTCH PPS payment types. A few of the commenters' analyses included assumptions about LTCH behavioral response to statutory changes to the LTCH PPS (such as changes in patient volume and costs). A few commenters indicated that using historical data would not reflect the anticipated behavioral response as a result of the new statutory payment structure and, therefore, may lead to an overestimation of costs and HCO payments (particularly with regard to payments for site neutral payment rate cases), resulting in a fixed-loss amount that is set too high relative to the HCO target. If this were to occur, these commenters expressed concern that LTCHs would be ''underpaid'' because HCO payments are budget neutral and actual HCO payments would fall below the HCO payments target.

In the FY 2016 IPPS/LTCH PPS proposed rule, we stated our appreciation for the commenters' detailed feedback and indicated that we had taken their concerns and recommendations into consideration while framing our proposed HCO policy under the new statutory LTCH PPS structure. As we always have for the LTCH PPS, we designed our proposed HCO policy under the new statutory structure to achieve a balance of the following goals: To reduce financial risk, reduce incentives to underserve costly beneficiaries, and improve the overall fairness of the PPS (67 FR 56023). With these goals in mind, we evaluated whether it would be appropriate to modify our current HCO policy to account for the establishment of the new dual rate LTCH PPS payment structure. This included examining whether our current HCO target, under which we set a single fixed-loss amount so that estimated total HCO payments are projected to equal 8 percent of estimated total LTCH PPS payments, should continue to be used upon implementation of the statutory LTCH PPS payment changes, or whether it would be more appropriate to have two separate HCO targets (one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases).

In examining this issue, we considered how LTCH discharges based on historical claims data would have been classified under the new dual rate LTCH PPS payment structure and the CMS' Office of the Actuary (OACT) projections regarding how LTCHs would likely respond to our proposed implementation of policies resulting from the statutory payment changes. For FY 2016, our actuaries currently project that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases verses site neutral payment rate cases under the new statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. (As previously noted, based on FY 2013 LTCH claims data, we found that approximately 54 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 46 percent of LTCH cases would have been paid the site neutral payment rate if those rates had been in effect at that time.) While our actuaries do not project an immediate change in these proportions, they do project cost and resource changes to take into account the lower payment rates. Our actuaries also project 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. 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, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. These assumptions are consistent with statements from several commenters who noted that the type of site neutral payment rate cases may change in cost and severity over time in response to the new statutory payment structure because the payment for those cases

would generally be lower than the current payment made under the LTCH PPS for these types of cases (80 FR 24538).

In light of these projections and expectations, we stated in the proposed rule that we believe that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. Currently, the FY 2015 LTCH PPS fixed-loss amount is $14,972, which was determined using FY 2013 LTCH claims data (79 FR 50400). The FY 2015 IPPS fixed-loss amount is $25,799 (79 FR 50374). A single fixed-loss amount and target under the LTCH PPS would allow LTCH cases paid at the site neutral payment rate to qualify for HCO payments much more easily than comparable IPPS cases assigned to the same MS–DRG. This would occur because the HCO threshold (which is generally the sum of the adjusted Federal PPS payment for the case and the fixed-loss amount) under the IPPS would be higher than the HCO threshold under the LTCH PPS for a case assigned to the same MS–DRG (which would be expected to have a comparable adjusted Federal PPS payment, costs and resource use to a case paid as a LTCH PPS site neutral payment rate case). We also stated in the proposed rule that while we recognize that differing statutory requirements between the two payment systems result in comparable LTCH PPS site neutral payment rate cases and IPPS cases not being paid exactly the same amount, 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. Based on the FY 2015 figures, an IPPS hospital would have to absorb approximately $11,000 more in additional estimated costs than the LTCH treating a comparable case based on the difference between the IPPS fixed-loss amount of $25,799 and the LTCH PPS fixed-loss amount of $14,792 before it would begin to receive HCO payments. We believe that the most appropriate fixed-loss amount for site neutral payment rate cases under the LTCH PPS for a given fiscal year beginning with FY 2016 would be the IPPS fixed-loss amount for that fiscal year. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24538 through 24539), for FY 2016, we proposed a fixed-loss amount for site neutral payment rate cases of $24,485, which was the same proposed FY 2016 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to the proposed rule and this final rule. We believe that this policy will 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. We also proposed to make a payment adjustment for HCOs paid under the site neutral payment rate at a rate equal to 80 percent of the difference between the estimated cost of the case and the proposed IPPS HCO threshold, which is consistent with the current LTCH PPS HCO policy. The proposed IPPS HCO threshold for site neutral payment rate cases would be the sum of the LTCH PPS payment for such cases and the proposed IPPS fixed-loss amount of $24,485. As stated above, we believe that this policy will 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. We also proposed to codify these proposals by making revisions to the existing HCO policy at § 412.525(a). In light of these proposals, we noted that any site neutral payment rate case that is paid 100 percent of the estimated cost of the case because that amount is lower than the IPPS comparable per diem amount will never be eligible to receive a HCO payment because, by definition, the estimated costs of such cases will never exceed the IPPS comparable per diem amount by any threshold.

Comment: Commenters supported the proposed HCO policy under the new statutory LTCH PPS structure, under which there would be separate HCO fixed-loss amounts and separate HCO payment targets for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases. Commenters also expressed support for the proposals concerning the methodology for determining the HCO payment amount for site neutral payment rate cases, including the use of the IPPS FLT for FY 2016. While commenters generally agreed with our assumptions that the costs and resource use for site neutral payment rate cases would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, some commenters also noted their belief that the type of site neutral payment rate cases may change in cost and severity over time in response to the new dual rate LTCH PPS payment structure. These commenters requested that CMS revisit the use of the IPPS fixed-loss amount once we have actual experience under the revised LTCH PPS, and possibly develop a HCO fixed-loss amount for site neutral payment rate cases that is independent of the IPPS's amount in the future. (Commenters also provided comments regarding the proposed budget neutrality adjustment for HCO payments to site neutral payment rate cases, which are discussed later in this section.)

Response: We appreciate the commenters' support of these proposals. As we indicated in the proposed rule, we believe having a single HCO policy for both standard Federal payment rate cases and site neutral payment rate cases under the revised LTCH PPS would be problematic in light of our projections and expectations of LTCHs' behavioral response to statutory changes to the LTCH PPS. We also explained that, given the expectation that cases paid at the site neutral payment rate would likely be similar to IPPS cases assigned to the same MS–DRG, the most appropriate fixed-loss amount for site neutral payment rate cases would be the IPPS fixed-loss amount for that fiscal year. To the extent experience under the revised LTCH PPS indicates site neutral payment rate cases differ sufficiently from these expectations, we agree it would be appropriate to revisit in future rulemaking the most appropriate fixed-loss amount used to determine HCO payments for site neutral payment rate cases.

After consideration of public comments we received, we are finalizing without modification our proposals to have separate HCO policies under the new dual rate LTCH PPS payment structure and our proposed methodology for calculating site neutral payment rate case the HCO payments, including the use of the IPPS FLT. We also are finalizing proposed revisions to the existing HCO policy at § 412.525(a) to codify these policies, as discussed below in this section.

Therefore, in this final rule, we are establishing a fixed-loss amount for site neutral payment rate cases for FY 2016 of $22,544, which was the same FY 2016 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to this final rule. As stated above, we believe that this policy will 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.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24539), after having established the IPPS fixed-loss amount as an appropriate threshold to propose for HCOs paid under the site neutral payment rate, we next examined how to establish an appropriate fixed-loss amount and HCO target for LTCH PPS standard Federal payment rate

cases. Therefore, we agreed with the commenters who recommended in response to our solicitation for input during the FY 2015 rulemaking cycle that we establish a fixed-loss amount and target for LTCH PPS standard Federal payment rate cases using the current LTCH PPS HCO policy, but limiting the data used under that policy to was and/or what would have been LTCH PPS standard Federal payment rate cases if the new dual rate LTCH PPS payment structure was/had been in effect at the time of those discharges. We also agreed with the commenters from the FY 2015 rulemaking cycle that believed this policy would result in increased stability over time with respect to HCO payments for the LTCH PPS standard Federal payment rate cases. We also believed that this approach would meet the goals cited for our revised and current HCO policy; that is, reducing financial risk, reducing incentives to underserve costly beneficiaries, and improving the overall fairness of the LTCH PPS (67 FR 56023). Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule, we did not propose to make any modifications to the HCO methodology as it applies to LTCH PPS standard Federal payment rate cases, other than determining a fixed-loss amount using only data from LTCH PPS standard Federal payment rate cases. Specifically, under our proposal, LTCH PPS standard Federal payment rate cases as described under proposed new § 412.522(a)(2) would receive an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which would be the sum of the LTCH PPS payment for the LTCH PPS standard Federal payment rate case and the fixed-loss amount for such cases. The fixed-loss amount for LTCH PPS standard Federal payment rate cases would continue to be determined so that estimated HCO payments would be projected to be equal to 8 percent of estimated total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In the FY 2016 IPPS/LTCH PPS proposed rule, to codify our proposed changes to the HCO policy to account for the new dual rate LTCH PPS payment structure, we proposed to revise paragraphs (a)(1), (a)(2), and (a)(3), and add a new paragraph (a)(4) to existing § 412.525. In existing § 412.525 (a)(1), (a)(2), and (a)(3), we proposed to make technical changes to the existing language to make it clear that the provisions in those paragraphs apply to LTCH discharges under both LTCH PPS payment rates (that is, site neutral payment rate cases as described at new § 412.522(a)(1) and the standard Federal payment rate cases as described at new § 412.522(a)(2)). Under the proposed new paragraph (a)(4) to § 412.525, we also proposed to specify what the terms ''applicable LTCH PPS prospective payment'' and ''applicable fixed-loss amount'' mean for purposes of this paragraph. Specifically, we proposed that, for purposes of § 412.525(a), ''applicable LTCH PPS prospective payment'' means either the site neutral payment rate under new § 412.522(c) for LTCH discharges described under new § 412.522(a)(1) or the standard Federal prospective payment rates under § 412.523 for LTCH discharges described under new § 412.522(a)(2). Similarly, we proposed that, for purposes of § 412.525(a), ''applicable fixed-loss amount'' means either, for LTCH described under new § 412.522(a)(1), the fixed-loss amount established for such cases, or, for LTCH discharges described under new § 412.522(a)(2), the fixed-loss amount established for such cases. In addition, we proposed to add language to paragraph (a) of § 412.525 to clarify that the fixed-loss is the maximum loss that a LTCH can incur under the LTCH PPS for a case with unusually high costs ''before receiving an additional payment,'' and is not the maximum loss an LTCH can incur. We proposed to make this clarification to highlight that the additional payment under the revised HCO policy is 80 percent (not 100 percent) of the estimated costs above the outlier threshold (that is, the sum of the applicable LTCH PPS prospective payment and the applicable fixed-loss amount).

Comment: Commenters supported the proposals to apply the existing HCO policy to LTCH PPS standard Federal payment rate cases, including the 8 percent HCO payment percentage target. However, some commenters requested that, when calculating the fixed-loss amount for cases that will be paid using the LTCH PPS standard Federal payment rate in FY 2016, CMS include all of the cases in the historical data that would have been paid using the LTCH PPS standard Federal payment rate had the revised FY 2016 LTCH PPS been in effect at the time of the discharge, not just the historical data for cases meeting the criteria for exclusion from the site neutral payment rate. These commenters believed that CMS' use of only the historical cases meeting the criteria for exclusion from the site neutral payment rate in the calculation of the fixed-loss amount for FY 2016 is inaccurate. They also stated that the proposed approach results in estimated aggregate FY 2016 high-cost outlier payments for cases paid using the LTCH PPS standard Federal payment rate that are less than 8 percent of estimated aggregate FY 2016 payments for such cases (that is, paid using the LTCH PPS standard Federal payment rate during FY 2016). These commenters also requested that CMS modify the proposed conforming changes to the existing HCO policy at § 412.525(a) to reflect their requested changes to the fixed-loss amount.

Response: We appreciate the commenters' support of our proposals to determine HCO for LTCH PPS standard Federal payment rate cases using our existing HCO policies, including the 8 percent HCO payment percentage target. We proposed that the fixed-loss amount for LTCH PPS standard Federal payment rate cases would continue to be determined so that estimated HCO payments would be projected to be ''equal to 8 percent of estimated total LTCH PPS payments for LTCH PPS standard Federal payment rate cases'' (80 FR 24539). In the proposed rule, we clearly indicated that the phrase ''LTCH PPS standard Federal payment rate case''' refers to a LTCH PPS case that meets the criteria for exclusion from the site neutral payment rate under section 1886(m)(6)(A)(ii) of the Act (80 FR 24527). The commenters' concern regarding the calculation of the fixed-loss amount for FY 2016 comes from the distinction between ''cases paid using the LTCH PPS standard Federal payment rate in FY 2016'' and ''LTCH PPS standard Federal payment rate cases in FY 2016.'' Under the statutory phase-in of the LTCH PPS for FY 2016, cases in an LTCH with a cost reporting period starting before October 1, 2015, that do not meet the criteria for exclusion from the site neutral payment rate will nevertheless be ''paid using the LTCH PPS standard Federal payment rate'' until the start of that LTCH's first cost reporting period beginning in FY 2016. These cases are the historical cases that the commenters requested be included in the calculation of the FY 2016 fixed-loss amount for ''LTCH PPS standard Federal payment rate cases'' even though those cases would not meet the criteria to be excluded from the site neutral payment rate had the revised LTCH PPS been in effect at the time of the discharge.

For the calculation of the fixed-loss amount in the second year of the revised LTCH PPS (that is, FY 2017), there is no difference between the historical cases that would have been paid using the LTCH PPS standard Federal payment

rate and the historical cases that would meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) had the revised FY 2017 LTCH PPS been in effect at the time of the discharge. The distinction between them under the revised FY 2016 LTCH PPS (explained above) no longer exists—they are the same cases. It is only in the first year of the revised LTCH PPS (FY 2016) that there is a difference. As explained above, this difference is due to the statutory phase-in of the revised LTCH PPS in FY 2016: cases in an LTCH with a cost reporting period starting before October 1, 2015, that do not meet the criteria for exclusion from the site neutral payment rate will continue to be paid at the higher LTCH PPS standard Federal payment rate until the start of that hospital's first cost reporting period in FY 2016.

We considered the approach requested by commenters of using the historical cases that would have been paid using the LTCH PPS standard Federal payment rate had the revised FY 2016 PPS been in effect at the time of the discharge to calculate the fixed-loss amount for FY 2016. However, we believe that approach would lead to less stability in the fixed-loss amount between FY 2016 and FY 2017 because cases not meeting the criteria for exclusion from the site neutral payment rate (had those criteria been in effect) would be included in the calculation of the fixed-loss amount for FY 2016 and then not included in the calculation for FY 2017. As we stated in the proposed rule, we believe our proposal would result in increased stability over time with respect to HCO payments for the LTCH PPS standard Federal payment rate cases (80 FR 24539). In addition, as noted earlier, there is uncertainty surrounding the site neutral payment rate case population under the new dual rate LTCH PPS payment structure. For the portion of the site neutral payment rate case population that will continue to be paid at the LTCH PPS standard Federal payment rate for a portion of FY 2016 (that is, those FY 2016 cases that would not meet the criteria for exclusion and would be paid the site neutral payment rate were those cases in LTCH cost reporting periods subject to those criteria at the time of the discharge), there is even greater uncertainty as to what the costs of those cases will be during that time. Therefore, we disagree that our proposed methodology is inaccurate. However, we acknowledge that these two approaches result in different estimated aggregate FY 2016 payments for cases paid using the LTCH PPS standard Federal payment rate, but that is due to the transitory effect of the statutory phase-in of the revised LTCH PPS. In FY 2017, the two approaches would result in the same estimated aggregate FY 2017 LTCH PPS expenditures.

After consideration of the public comments we received, for the reasons discussed, we are finalizing our policy as proposed without modification. In this final rule, we are calculating the fixed-loss amount for FY 2016 so that estimated aggregate FY 2016 HCO payments for cases that meet the criteria for exclusion from the site neutral payment rate are estimated to be equal to 8 percent of estimated aggregate FY 2016 payments for cases that meet the criteria for exclusion from the site neutral payment rate, rather than calculating the fixed-loss amount so that estimated aggregate FY 2016 HCO payments for cases paid using the LTCH PPS standard Federal payment rate are estimated to be equal to 8 percent of estimated aggregate FY 2016 payments for cases paid using the LTCH PPS standard Federal payment rate. We also are finalizing our proposals, without modification, to codify the changes to the HCO policy to account for the new dual rate LTCH PPS payment structure in existing § 412.525.

The current LTCH PPS HCO policy has a budget neutrality requirement in which the LTCH PPS standard Federal payment rate is reduced by an adjustment factor to account or the estimated proportion of HCO payments to total estimated LTCH PPS payments, that is, 8 percent. (We refer readers to § 412.523(d)(1) of the regulations.) This budget neutrality requirement is intended to ensure that the HCO policy would not result in any change in estimated aggregate LTCH PPS payments. Under our proposal to continue to apply the current HCO methodology as it relates to LTCH PPS standard Federal payment rate cases (other than determining a fixed-loss amount using only data from LTCH PPS standard Federal payment rate cases (had the new statutory patient criteria been in effect at the time of the discharge), we also would continue to apply the current budget neutrality requirement (described above). In accordance with the current LTCH PPS HCO policy budget neutrality requirement, we believe that the HCO policy for site neutral payment rate cases should also be budget neutral, meaning that the proposed site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments. In order to achieve this, under new § 412.522(c)(2)(i), we proposed to apply a budget neutrality factor to the payment for all site neutral payment rate cases described under proposed new § 412.522(a)(1), which would also be established on an estimated basis. This approach was consistent with the HCO policy proposed LTCH PPS standard Federal payment rate cases HCO policy, which is budget neutral within the universe of LTCH PPS standard Federal payment rate cases (had the new statutory patient criteria been in effect at the time of the discharge). We invited public comments on this approach and the alternative approach of applying a single budget neutrality factor to all LTCH PPS cases, irrespective of the site neutral payment rate.

In order to estimate the magnitude a proposed budget neutrality adjustment under our proposed HCO payment budget neutrality requirement for site neutral payment rate cases, we again relied on the assumption by our actuaries that site neutral payment rate cases would have lengths of stay and costs comparable to IPPS cases assigned to the same MS–DRG. Under the IPPS, the fixed-loss amount is estimated based on a 5.1 percent target (79 FR 50378). In accordance with section 1886(d)(5)(A)(iv) of the Act, estimated operating IPPS HCO payments for any year are projected to be at least 5 percent, but no more than 6 percent of estimated total operating DRG payments, which does not include IME and DSH payments plus HCO payments. When setting the HCO threshold, we historically compute a 5.1 percent target by dividing the total operating IPPS HCO payments by the total operating IPPS DRG payments plus operating IPPS HCO payments (79 FR 50374). We believe that it is reasonable to set the site neutral payment rate case HCO target at the IPPS HCO target because these cases are expected to have lengths of stay and costs comparable to IPPS cases assigned to the same MS–DRG. Furthermore, using the IPPS fixed-loss threshold for the site neutral payment rate cases would be expected to result in HCO payments for site neutral payment rate cases that are similar in proportion as is seen in IPPS cases assigned to the same MS–DRG; that is, 5.1 percent. We recognize that, given the uncertainty surrounding the site neutral payment rate case population under the revised LTCH PPS and differences between the relative utilization of the MS–DRGs and MS–LTC–DRGs between the two systems, this prediction may not

take effect. However, we must begin somewhere, and we believed that this proposed policy seems to be the best budget neutrality option at this time based on the information available to ensure LTCH PPS spending does not inappropriately increase under our proposal for site neutral payment rate HCO cases. As with all of our finalized policies, we will continue to monitor HCOs payments under the LTCH PPS and, as necessary, propose modifications to the proposed method as needed based on what is observed during the implementation process.

Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24540 through 24541), under proposed new § 412.522(c)(2)(i), we proposed to adjust payments to site neutral payment rate cases (that is, LTCH PPS discharges described under proposed new § 412.522(a)(1)) by a budget neutrality factor so that the estimated HCO payments payable to site neutral payment rate cases do not result any increase in aggregate LTCH PPS payments. As discussed in greater detail in section V.D.4. of the Addendum to the proposed rule and this final rule, in estimating total LTCH PPS payments in Federal FY 2016, we proposed to apply an adjustment to account for the varying effective dates of the statutory LTCH PPS payment changes required by section 1886(m)(6) of the Act, as amended by section 1206 of Public Law 113–67, which are effective for discharges occurring in cost reporting periods beginning on or after October 1, 2015.

Comment: Commenters objected to the proposed site neutral payment rate HCO budget neutrality adjustment, claiming that it would result in savings instead of being budget neutral. The commenters' primary objection was based on their belief that, because the IPPS base rates used in the IPPS comparable per diem amount calculation of the site neutral payment rate include a budget neutrality adjustment for IPPS HCO payments (for example, a 5.1 percent adjustment on the operating IPPS standardized amount), an ''additional'' budget neutrality factor is not necessary and is, in fact, duplicative. Based on their belief that the proposed site neutral payment rate HCO budget neutrality adjustment is duplicative, some commenters recommended that if CMS continues with the application of that budget neutrality adjustment, the calculation of the IPPS comparable per diem amount should be revised to use the IPPS operating standardized amount prior to the application of the IPPS HCO budget neutrality adjustment. The commenters also disagreed with CMS' proposed approach for determining the proposed site neutral payment rate HCO budget neutrality factor, and also noted some technical changes to the calculation should CMS finalize this proposal.

Response: We disagree with the commenters that a budget neutrality adjustment for site neutral payment rate HCO payments is unnecessary or duplicative. While the commenters are correct that the IPPS base rates that are used in site neutral payment rate calculation include a budget neutrality adjustment for IPPS HCO payments, that adjustment is merely a part of the calculation of one of the inputs (that is, the IPPS base rates) that are used in the LTCH PPS computation of site neutral payment rate. The HCO budget neutrality factor that is applied in determining the IPPS base rates is intended to fund estimated HCO payment made under the IPPS, and is therefore determined based on estimated payments made under the IPPS. As such, the HCO budget neutrality factor that is applied to the IPPS base rates does not account for the additional HCO payments that would be made to site neutral payment rate cases under the LTCH PPS. Without a budget neutrality adjustment when determining payment for a case under the LTCH PPS, any HCO payment payable to site neutral payment rate cases would increase aggregate LTCH PPS payments above the level of expenditure if there were no HCO payments for site neutral payment rate cases. Therefore, our proposed approach appropriately results in LTCH PPS payments to site neutral payment rate cases that are budget neutral relative to a policy with no HCO payments to site neutral payment rate cases. For these reasons, we are not adopting the commenters' recommendation to change the calculation of the IPPS comparable per diem amount to adjust the IPPS operating standardized amount used in that calculation to account for the application of the IPPS HCO budget neutrality adjustment.

After consideration of the public comments we received, for the reasons discussed above, we are adopting our proposal to adjust payments to site neutral payment rate cases by a budget neutrality factor so that the estimated HCO payments payable to site neutral payment rate cases do not result any increase in aggregate LTCH PPS payments (relative to LTCH PPS payments without HCO payments to site neutral payment rate cases), without modification. In doing so, we note that we present and respond to the comments on CMS' proposed approach for determining the proposed site neutral payment rate budget neutrality factor, including the technical changes recommended by some commenters, in section V.D.4. of the Addendum to this final rule.

In addition to the proposed changes to the existing HCO policy under § 412.525(a) and the budget neutrality adjustment to account for site neutral payment rate HCO payments under proposed § 412.522(c)(2)(i), we proposed to make conforming changes to existing § 412.523 under paragraph (d)(1) to specify that the HCO target of 8 percent in that provision only applies to HCO payments under § 412.525(a) as they relate to LTCH PPS standard Federal payment rate cases; that is, HCO payments made for discharges described under proposed new § 412.522(a)(2) and not all HCO payments described under proposed new § 412.525(a).

We did not receive any public comments on the proposed conforming changes to existing § 412.523(d)(1). Therefore, we are adopting these changes as final without modification.

In summary, in this final rule, we are finalizing the policy to have separate HCO fixed-loss amounts and HCO targets (and corresponding budget neutrality adjustments) for site neutral payment rate cases and LTCH PPS standard Federal payment rate cases, respectively, under the new dual rate LTCH PPS payment structure. For the reasons discussed above, we believe that separate and independent HCO fixed-loss amounts for each of the two types of LTCH PPS cases will result in the most appropriate payments under the LTCH PPS and achieve the stated goals of our HCO policy. In accordance with our revised HCO policy for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases, we are establishing that, beginning with FY 2016, our current HCO policy will apply to LTCH PPS standard Federal payment rate cases, such that LTCH PPS standard Federal payment rate cases will receive an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the LTCH PPS standard Federal payment HCO threshold (which is the sum of the LTCH PPS standard Federal payment rate for the case and the fixed-loss amount for such cases). The fixed-loss amount for LTCH PPS standard Federal payment rate cases will be determined so that estimated HCO payments will be projected to equal 8 percent of estimated total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. To maintain budget neutrality, the LTCH PPS standard Federal payment rate will

continue to be adjusted by 8 percent to account for the estimated HCO payments to LTCH PPS standard Federal payment rate cases. Similarly, we are establishing that site neutral payment rate cases will receive an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the site neutral payment rate HCO threshold, which is the sum of site neutral payment rate for the case and the fixed-loss amount for such cases. For site neutral payment rate cases, we are finalizing the proposal to use the fixed-loss amount determined annually under the IPPS HCO policy, and we estimate that this will result in an estimated proportion of HCO payments to total LTCH PPS payments for site neutral payment rate cases of 5.1 percent. We are establishing that HCO payments to site neutral payment rate cases will be budget neutral, consistent with the current LTCH PPS HCO policy. To maintain budget neutrality, we are finalizing the proposal to apply a budget neutrality factor to the LTCH PPS payments for site neutral payment rate cases. (The details of the determination of the site neutral payment rate HCO budget neutrality factor are discussed in section V.D.4. of the Addendum to this final rule.) To codify the policies discussed in this section, we are making changes to the existing HCO policy under § 412.525(a) and conforming changes to existing § 412.523(d)(1), as well as a budget neutrality requirement for HCO payments to site neutral payment rate cases under new § 412.522(c)(2)(i).

c. Limitation on Charges to Beneficiaries

In accordance with existing regulations and for the consistency with other established hospital prospective payment systems polices, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24541), we proposed to revise § 412.507 to establish allowable charges to Medicare beneficiaries whose discharge from the LTCH is paid under the site neutral payment rate (as described in section VII.B.4. of the preamble of the proposed rule and this final rule). Section 1206(a)(1) of Public Law 113–67 requires that, beginning with cost reporting periods occurring on or after October 1, 2015, all LTCH discharges be paid at the applicable site neutral payment rate unless certain criteria are met. In general, the site neutral rate payment is based on the lesser of 100 percent of the estimated cost of the case or the IPPS comparable per diem amount (as discussed more detail in section VII.B.4.a. of the preamble of this final rule). We believe that, in general, the LTCH PPS payment an LTCH receives at the site neutral payment rate represents a full payment for purposes of determining allowable beneficiary charges for covered services. As such, using the broad authority conferred upon the Secretary under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, in the proposed rule, we proposed to revise § 412.507 to limit allowable charges to beneficiaries. Specifically, we proposed that, if Medicare has paid the full site neutral payment rate for a discharge, an LTCH may only charge the beneficiary applicable deductibles and copay amounts until the high-cost outlier threshold is met. In addition, we proposed to revise the terminology used under § 412.507 to differentiate between cases paid under the site neutral payment rate and those paid under the LTCH PPS standard Federal payment rate. We noted that, under this proposed revision, for a case paid under the site neutral payment rate, that payment applies to the LTCH's costs for services furnished until the high-cost outlier threshold is met, and LTCHs may charge the beneficiary for noncovered services in the same manner as if the case were paid under the LTCH PPS standard Federal payment rate, as specified under existing § 412.507. We did not propose to make any additional changes to our current provisions limiting charges to beneficiaries for discharges paid as SSO cases because, as explained in section VII.B.5. of the preamble of the proposed rule and this final rule, we did not propose to adopt any SSO payment adjustment policies for discharges paid under the site neutral payment rate at this time. We stated that we believe that these proposals concerning the limitation on charges to beneficiaries are in accordance with existing regulations and consistent with other established hospital payment systems policies.

We did not receive any public comments concerning our proposed changes to the regulations limiting charges to beneficiaries. Therefore, we are finalizing, without modification, our proposals to limit charges to beneficiaries.

C. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2016

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 753 MS–DRG groupings. For FY 2016, there are 758 MS–DRG groupings that we are

finalizing in conjunction with all of the changes discussed in section II.G. of the preamble of this final 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. Below we provide a general summary of our existing methodology for determining the FY 2016 MS–LTC–DRG relative weights under the LTCH PPS.

In this final rule, in general, for FY 2016, we are using our existing methodology to determine the MS–LTC–DRG relative weights (as discussed in greater detail in section VII.C.3. of the preamble of this final rule). However, under the new dual rate LTCH PPS payment structure, we are establishing that, beginning with FY 2016, the annual recalibration of the MS–LTC–DRG relative weights will be 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 were in effect when claims data from time periods before the new dual rate LTCH PPS payment structure applies were 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. 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 in greater detail in section VII.C.3.c. of the preamble of this final rule). In addition, we are continuing 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.C.3.c. of the preamble of this final rule.

Under our finalized policies, the MS–LTC–DRG relative weights will not be used to determine the LTCH PPS payment for cases paid at the site neutral payment rate and data from cases paid at the site neutral payment rate or that would have been paid at the site neutral payment if the dual rate LTCH PPS payment structure had been in effect will not be used to develop the relative weights. (For details on our finalized policies regarding the application of the site neutral payment rate, we refer readers to section VII.B. of the preamble of this final rule. For additional information on our finalized policy to use data from applicable LTCH cases to determine the MS–LTC–DRG relative weights under the new dual rate LTCH PPS payment structure, we refer readers to section VII.B.7.a. of the preamble of this final rule.)

Furthermore, for FY 2016, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, we will 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 payment rate 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.C.3.g. of the preamble of this final 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 above 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–9–CM 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 86.11)) 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 and that payment varies by the MS–LTC–DRG to which a beneficiary's stay 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 on the 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 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).

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 Internal Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). For additional information on the ICD–9–CM coding system, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47241 through 47243 and 47277 through 47281). We also refer readers to the detailed discussion on correct coding practices in the August 30, 2002 LTCH PPS final rule (67 FR 55981 through 55983).

Currently, providers use the code sets under the ICD–9–CM coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system. We have been discussing the conversion to the ICD–10 coding system for many years. Hospitals, including LTCHs, are required to use the ICD–10 coding system effective October 1, 2015. Consequently, providers will begin using the code sets under the ICD–10 coding system to report diagnoses (ICD–10–CM codes) and procedures (ICD–10–PCS codes) for Medicare hospital inpatient services under the MS–DRG system (and by extension the MS–LTC–DRG system) beginning October 1, 2015. For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.G.1. of the preamble of this final 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 development (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 Medicare contractor 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 Medicare contractor 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. Changes to the MS–LTC–DRGs for FY 2016

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, we are updating the MS–LTC–DRG classifications effective October 1, 2015, through September 30, 2016 (FY 2016) consistent with the changes to specific MS–DRG classifications presented in section II.G. of the preamble of this final rule. Therefore, the MS–LTC–DRGs for FY 2016 presented in this final rule are the same as the MS–DRGs that are being used under the IPPS for FY 2016. Specifically, as discussed in section II.G.1.b. of this preamble of this final rule, we are using the ICD–10 MS–DRGs Version 33 as the replacement logic for the ICD–9–CM based MS–DRGs Version 32 as part of the MS–DRG updates (and by extension the MS–LTC–DRG) updates for FY 2016. The GROUPER Version 33 is based on ICD–10–CM/PCS diagnoses and procedure codes, consistent with the requirement to use ICD–10 beginning October 1, 2015, as noted above and discussed in greater detail in section II.G.1. of the preamble of this final rule.

In the proposed rule, we invited public comments on how well the ICD–10 MS–DRGs Version 33 (and by extension the ICD–10 MS–LTC–DRGs Version 33) replicates the logic of the ICD–9 MS–DRGs Version 32 (and by extension ICD–9 MS–LTC–DRGs Version 32). These comments and our responses are discussed in section II.G.1.a. of the preamble of this final rule. (We note that, when referencing MS–LTC–DRGs Version 33 in the remainder of this section, we are referring to the ICD–10-based MS–LTC–DRGs Version 33 unless otherwise stated. Similarly, when referencing MS–LTC–DRGs Version 32 for the remainder of this section, we are referring to the ICD–9-based MS–LTC–DRGs Version 32 unless otherwise stated.) In addition, because the MS–LTC–DRGs for FY 2016 are the same as the MS–DRGs for FY 2016, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under GROUPER Version 33, as discussed in section II.G. of the preamble of this final rule, including the changes to the MCE software and the ICD–10 coding system, will also be applicable under the LTCH PPS for FY 2016.

3. Development of the FY 2016 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 system rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual

adjustments under the new dual rate LTCH PPS payment structure, as previously discussed in section VII.B.7.a. of the preamble of this final rule, we are finalizing the policy, beginning with FY 2016, to recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases. Under this policy, the resulting MS–LTC–DRG relative weights will continue to be used to adjust the LTCH PPS standard Federal rate when calculating the payment for LTCH PPS standard Federal payment rate cases. However, the MS–LTC–DRG relative weights will not be used to determine the LTCH PPS payment for cases paid under the site neutral payment rate. (For details on our finalized policies regarding application of the site neutral payment rate, we refer readers to section VII.B. of the preamble of this final rule.)

The established methodology to develop the MS–LTC–DRG relative weights is 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), with the exception of 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. (For details on these 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).) 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 a MS–LTC–DRG with a relative weight of 2 will, on average, cost twice as much to treat as cases in a MS–LTC–DRG with a relative weight of 1.

b. Development of the MS–LTC–DRG Relative Weights for FY 2016

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50170 through 50176), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2015.

In this final rule, as proposed, we are continuing to use our existing methodology to determine the MS–LTC–DRG relative weights for FY 2016, including the application of established policies related to, the hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, and the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor. However, as previously noted and discussed in greater detail in section VII.B.7.a. of the preamble of this final rule, under the new dual rate LTCH PPS payment structure, after consideration of public comments, as we proposed, we are establishing that the FY 2016 MS–LTC DRG relative weights will be determined based only on data from applicable LTCH cases (which includes our finalized policy of using only cases that would meet the criteria for exclusion from the site neutral payment rate (had those criteria been in effect at the time of the discharge)). We discuss the effects of our finalized policies concerning the data used to determine the FY 2016 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

Furthermore, as we have done since the FY 2008 update, and as we proposed, we are applying a two-step budget neutrality adjustment to the annual update to the MS–LTC–DRG classifications and relative weights at § 412.517(b) (in conjunction with § 412.503), 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 classification and relative weight changes (72 FR 26882 through 26884). For additional information on the established two-step budget neutrality methodology, we refer readers to the FY 2008 IPPS final rule (72 FR 47295 through 47296). Below we present our proposed methodology for determining the proposed MS–LTC–DRG relative weights for FY 2016 LTCH PPS standard Federal payment rate payments, which is generally consistent with our existing methodology, except for the proposed use of applicable LTCH data.

c. Applicable LTCH Data

For this final rule, to calculate the MS–LTC–DRG relative weights for FY 2016 LTCH PPS standard Federal payment rate payments, we obtained total charges from FY 2014 Medicare LTCH claims data from the March 2015 update of the FY 2014 MedPAR file, which are the best available data at this time, and the finalized Version 33 of the GROUPER to classify LTCH cases. Consistent with our historical practice and as we proposed, we are using those data and the finalized Version 33 of the GROUPER in establishing the FY 2016 MS–LTC–DRG relative weights in this final rule. To calculate the FY 2016 MS–LTC–DRG relative weights under the new dual rate LTCH PPS payment structure that will be effective beginning October 1, 2015, beginning with the annual recalibration of the MS–LTC–DRG relative weights for FY 2016, we are using applicable LTCH data, which, as previously discussed in section VII.B.7.a. of this preamble of, includes our finalized policy of using only cases that meet the criteria for exclusion from the site neutral payment rate (or would meet the criteria had they been in effect at the time of the discharge). Accordingly, as we proposed, we began by first evaluating the LTCH claims data in the March 2015 update of the FY 2014 MedPAR file to determine which LTCH cases would have met the criteria for exclusion from the site neutral payment rate under § 412.522(b) (as discussed in greater detail in section VII.B.3. of the preamble of this final rule) had the new dual rate LTCH PPS payment structure been in effect at the time of discharge. We identified the FY 2014 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, under our finalized policies, will identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation (as discussed in section VII.B.3.b. of the preamble of this final rule); 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 (discussed in section VII.B.3.e. of the preamble of this final rule); 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 (discussed in section VII.B.3.f. of the preamble of this final rule).

Claims data from the March 2015 update of the FY 2014 MedPAR file that reported ICD–9–CM procedure code

96.72 were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. (We note that the corresponding ICD–10–PCS code for cases involving at least 94 hours of ventilation services is 5A1955Z, effective as of October 1, 2015.)

Then, consistent with our historical methodology and as we proposed, we excluded any claims in the resulting data set that were submitted by LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed 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 as we proposed, we excluded the Medicare Advantage (Part C) claims that were in the resulting data set 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 relative weights for the LTCH PPS standard Federal payment rate payments for FY 2016.

In summary, in identifying the claims data for the development of the FY 2016 MS–LTC–DRG relative weights in this final rule, we are using claims data after we trim the claims data of 10 all-inclusive rate providers reported in the March 2015 update of the FY 2014 MedPAR file, as well as any Medicare Advantage claims data for cases that would have met the criteria for exclusion from the site neutral payment rate under § 412.522(b) if the new dual rate LTCH PPS payment structure were in effect at the time of discharge. (We note, there were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2015 update of the FY 2014 MedPAR file. However, had there been we would we trim the claims data from those LTCHs as well, in accordance with our established policy.) We are using the remaining data (that is, the applicable LTCH data) to calculate the relative weights for the LTCH PPS standard Federal payment rate payments for FY 2016. We note, the public comments we received, our responses to those comments, and our finalized policy of using only cases that would meet the criteria for exclusion from the site neutral payment rate (had those criteria been in effect at the time of the discharge) for the annual recalibration of the MS–LTC–DRG relative weights beginning for FY 2016 is presented in section VII.B.7.a. of this preamble of this final rule. We did not receive any public comments on the other parts of our proposals on the applicable LTCH data used to determine the relative weights for MS–LTC–DRGs for FY 2016, and are adopting those proposals as final without change.

After consideration of the public comments we received, we are finalizing our proposals on the applicable LTCH data used to determine the relative weights for MS–LTC–DRGs for FY 2016 without change.

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, as proposed, we are continuing to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2016 LTCH PPS standard Federal payment rate payments. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we are reducing 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 a 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 2016, we standardized 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.C.3.g. (Step 3) of the preamble of this final rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio was multiplied by that LTCH's case-mix index to determine the standardized charge for the case (67 FR 55989).

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 a LTCH with higher average costs than they would at a 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. Because we standardized charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a $10,000 charge for a case at a 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 a 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.

We did not receive any public comments concerning our proposal to continue to use HSRV methodology to determine the MS–LTC–DRG relative weights for FY 2016, and therefore, we are finalizing this proposed policy, without modification.

e. Treatment of Severity Levels in Developing the 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 below) 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 2016, we are using applicable LTCH cases to establish the same volume-based categories to calculate the FY 2016 relative weights for LTCH PPS standard Federal payment rate payments. This approach is consistent with our policies regarding the continued use of our existing methodology related to the treatment of severity levels as presented in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50172).

We provide in-depth discussions of our finalized policy regarding weight-setting for low-volume MS–LTC–DRGs in section VII.C.3.f. of the preamble of this final rule and for no-volume MS–LTC–DRGs, under Step 5 in section VII.C.3.g. of the preamble of this final rule.) Furthermore, in determining the FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments, when necessary, as proposed, we made adjustments to account for nonmonotonicity, as discussed in greater detail below in Step 6 of section VII.C.3.g. of the preamble of this final 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. Low-Volume MS–LTC–DRGs

In order to account for MS–LTC–DRGs for LTCH PPS Standard Federal payment rate cases with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology for purposes of determining the FY 2015 MS–LTC–DRG relative weights, as proposed, we are employing the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995 and 72 FR 47283 through 47288). In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile resulted in nonmonotonicity within a base-DRG, as proposed, we made adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail below in section VII.C.3.g. (Step 6) of the preamble of this final rule.

In the proposed rule, using the most current available data at that time, we noted our identification of 250 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. Based on the best available data for this final rule (that is, the March 2015 update of the FY 2014 MedPAR files, we now identified 251 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing 50 MS–LTC–DRGs (251/5 = 50, with a remainder of 1). We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for the proposed rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was evenly divisible by 5. Therefore, it was not necessary to employ our historical methodology for determining which of the low-volume quintiles contain an additional low-volume MS–LTC–DRG. However, for this final rule, based on the most current data available at this time, because the number of MS–LTC–DRGs with less than 25 applicable LTCH cases has shifted to 251 (which does not divide evenly), as proposed, we used our historical methodology for determining which quintiles would contain the additional MS–LTC–DRGs. Specifically for this final rule, after organizing the MS–LTC–DRGs by ascending order by average charge, we assigned the first fifth (1st through 50th) of low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The 50 MS–LTC–DRGs with the highest average charge cases were assigned into Quintile 5. Because the average charge of the 151st low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 150th low-volume MS–LTC–DRG (assigned to Quintile 3) than to the average charge of the 152nd low-volume MS–LTC–DRG (assigned to Quintile 4), we are assigning it to Quintile 3 (such that Quintile 3 contains 51 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This results in 4 of the 5 low-volume quintiles containing 50 MS–LTC–DRGs (Quintiles 1, 2, 4 and 5) and one low-volume quintile containing 51 MS–LTC–DRGs (Quintiles 3). Table 13A, listed in section VI. of the Addendum to this final rule and available via the Internet, lists the composition of the low-volume quintiles for MS–LTC–DRGs for FY 2016.

Accordingly, in order to determine the FY 2016 relative weights for the MS–LTC–DRGs with low-volume, as proposed, we are using the five low-volume quintiles described above. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in section VII.C.3.g. of the preamble of this final rule. As we proposed, we assigned the same relative weight and average length of stay to each of the 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 will 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 for LTCH PPS standard Federal payment rate payments result in appropriate payment for LTCH cases that will be grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

We did not receive any public comments concerning our proposals related to low-volume MS–LTC–DRGs. Therefore, we are finalizing, without modification, these proposals.

g. Steps for Determining the FY 2016 MS–LTC–DRG Relative Weights

In this final rule, as proposed, we are generally using our existing methodology to determine the FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments. However, in doing so, we are using only applicable LTCH cases and data to determine the FY 2016 MS–LTC–DRG relative weights (including our finalized policy of using only cases that met or would have met the criteria for exclusion from the site neutral payment rate (had those criteria been in effect at the time of the discharge as discussed in section VII.B.7.a. of the preamble of this final rule).

Comment: Based on their analysis of the proposed FY 2016 MS–LTC–DRG weights, some commenters stated that there may be reversal in the description of the steps of the CMS methodology for

calculating the MS–LTC–DRG relative weights. Commenters also noted that the data trimming in the step to remove statistical outliers appears to only address the removal of statistical outliers based on total charges and not the total charges per day requirement.

Response: We reexamined the description of the methodology for calculating the MS–LTC–DRG relative weights and found an inadvertent error in the order in which we have been presenting steps 1 and 2 of our methodology. Under our longstanding historical methodology to calculate the MS–LTC–DRG relative weights, we first remove cases with a length of stay of 7 days or less (which has been mistakenly described at step 2 in our methodology) and then remove statistical outliers (which has been mistakenly described at step 1 in our methodology). Cases with a length of stay of 7 days or less are removed in the initial step because leaving them in would distort the relative weights of the MS–LTC–DRGs. It is essential to remove such cases prior to trimming for statistical outliers in order to appropriately identify aberrant data when removing statistical outliers that would distort the measure of average resource use reflected in the MS–LTC–DRG relative weights. We thank commenters for pointing out this error in the description of the methodology. We note that the differences between applying steps 2 and 1 in the correct order (as we have always calculated these values) as opposed to the reversed order described in the proposed rule have heretofore been negligible (in fact, our understanding is that certain outside parties have replicated and/or performed analyses of the MS–LTC–DRG relative weights in prior years). However, under our finalized policy to use only cases that would meet the criteria for exclusion from the site neutral payment rate (had those criteria been in effect at the time of the discharge), the new dual rate LTCH PPS payment structure has reduced the number of cases we are using to calculate MS–LTC–DRG relative weights, making the description/order of the steps more significant. We appreciate the commenters bringing this to our attention and regret any confusion caused by our misstatement regarding the order of the steps one must take to calculate relative weights. We assure the industry that since the advent of the LTCH PPS we have been calculating these values by first removing the cases with an average length of stay of 7 days or less, and then removing statistical outliers. In addition, we agree with commenters that, for the FY 2016 proposed rule, we made a technical error in our application of the data trimming to remove statistical outliers. We appreciate commenters bringing this to our attention and the MS–LTC–DRG relative weights calculated for this final rule reflect the correct application of the data trimming. That is, we have ensured that to identify statistical outliers, we have applied the trim based on both charges per case and the charges per day (see step 2 below), consistent with our longstanding methodology.

After consideration of the public comments we received, we are finalizing our proposal to continue to use our existing methodology to calculation the MS–LTC–DRG relative weights for FY 2016, including calculating the values in the ordered steps we have employed in this calculation from the onset of the LTCH PPS. To reflect this, in this final rule, we are correcting the order of steps described in this preamble to reflect the order in which they have been, and will continue to be applied in the application of our existing policy.

In summary, to determine the FY 2016 MS–LTC–DRG relative weights, we grouped applicable LTCH cases to the appropriate MS–LTC–DRG, while taking into account the low-volume quintiles (as described above) and cross-walked no-volume MS–LTC–DRGs as described below. After establishing the appropriate MS–LTC–DRG (or low-volume quintile), we calculated the FY 2016 relative weights for LTCH PPS standard Federal payment rate payments by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2 below). Next, we adjusted the number of applicable LTCH cases in each MS–LTC–DRG (or 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) and, which are the SSO-adjusted applicable LTCH cases and corresponding charges (step 3 below), we calculated ''relative adjusted weights'' for each MS–LTC–DRG (or low-volume quintile) using the HSRV method. Below we discuss in detail the steps for calculating the FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our calculation of the FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments 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 a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the FY 2016 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments, we removed LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what would be 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 calculation of the FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments 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, as proposed, we are continuing 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 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 relative weights for LTCH PPS standard Federal payment rate payments 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 would be removed in this step of the 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 final rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 3—Adjust charges for the effects of SSOs.

As the next step in the calculation of the FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments, consistent with our historical approach, we adjusted 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 made 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 FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments will lower the FY 2016 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases will bring down the average charge for all cases within a MS–LTC–DRG. This will result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, as proposed, we are continuing to adjust for SSO cases under § 412.529 in this manner because it results 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 FY 2016 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we then calculated the FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculated a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio was then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 was used for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2016 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases (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 MS–LTC–DRG) for the 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 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 above) were then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values were then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process was continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001. (We note that, although we are not making any changes to this step of our relative weight methodology in this final rule, we have made some minor changes to the description of this step to clarify the application of our existing policy.)

Step 5—Determine a FY 2016 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, we identified the MS–LTC–DRGs for which there were no claims in the March 2015 update of the FY 2014 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we are generally assigning a relative weight to each of the no-volume MS–LTC–DRGs for LTCH PPS standard Federal payment rate cases based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed below). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

As proposed, we are cross-walking each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology described above). Then, the ''no-volume'' MS–LTC–DRG was assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail below).

Of the 758 MS–LTC–DRGs for FY 2016, we identified 367 MS–LTC–DRGs for which there are no trimmed applicable LTCH cases (the number identified includes no trimmed applicable LTCH cases in 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). As proposed, we are assigning relative weights to each of the 342 no-volume MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to one of the remaining 391 (758—367= 391) MS–LTC–DRGs for which we were able to calculate relative weights based on the trimmed applicable LTCH cases in the FY 2014 MedPAR file data using the steps described above. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as the MS–LTC–DRGs to which we cross-walked one of the 342 ''no volume'' MS–LTC–DRGs.) Then, we generally assigned the 342 no-volume MS–LTC–DRG the relative weight of the cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

As proposed, we cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we were able to calculate relative weights based on the March 2015 update of the FY 2014 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 MS–LTC–DRGs in FY 2015, the relative weights assigned based on the cross-walked 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 relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2016. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology described in Steps 1 through 4 above) was assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to one of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2016. (As we noted above, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments as described in Step 6 were required in order to maintain monotonically increasing relative weights.)

For this final rule, a list of 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) for FY 2016 is shown in Table 13B, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site.

To illustrate this methodology for determining the relative weights for the FY 2016 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume MS–LTC–DRGs crosswalk information for FY 2016 provided in Table 13B.

Example: There were no trimmed applicable LTCH cases in the FY 2014 MedPAR file that we are using for this final rule for MS–LTC–DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS–LTC–DRG 70 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to MS–LTC–DRG 61. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 70 of 0.9070 for FY 2016 to MS–LTC–DRG 61 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site).

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. As proposed, we are using the most recent available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in this final rule.

For FY 2016, consistent with our historical relative weight methodology, as we proposed, we are establishing 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 1); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 2); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 5); Liver Transplant without MCC (MS–LTC–DRG 6); Lung Transplant (MS–LTC–DRG 7); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 8); Pancreas Transplant (MS–LTC–DRG 10); and Kidney Transplant (MS–LTC–DRG 652). This is because Medicare will only cover 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 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 and as we proposed, we are establishing 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.

In the proposed rule, for FY 2016, we proposed to establish a relative weight equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). Under our proposed implementation of the new dual rate LTCH PPS payment structure, LTCH discharges that are grouped to these 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs would not meet the criteria for exclusion from the site neutral payment rate. As such, under our proposed implementation of the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation (which we are finalizing, as discussed in section VII.B.3.b. of the preamble of this final rule), there are no applicable LTCH cases to use in calculating a relative weight for the ''psychiatric and rehabilitation'' MS–LTC–DRGs. In other words, any LTCH PPS discharges grouped to any of the 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs will always be paid at the site neutral payment rate, and, therefore, those MS–LTC–DRGs will 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 will be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. Under the transitional payment method

for cases for site neutral payment rate cases discussed in detail in section VII.B.4.b. of the preamble of this final rule, 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), site neutral payment rate cases will be 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'' MS–LTC–DRGs in FY 2016, in the proposed rule, we proposed to assign a relative weight to these MS–LTC–DRGs for FY 2016, that would be the same as the FY 2015 relative weight. We believe that using the respective FY 2015 relative weight for each of the ''psychiatric or rehabilitation'' MS–LTC–DRGs would result in appropriate payments for LTCH cases that will be 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 were able to determine relative weights based on applicable LTCH cases in the FY 2014 MedPAR file data using the steps described above. Furthermore, we believe that it would be administratively burdensome and introduce unnecessary complexity to the MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a relative weight for those 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs to be used for the sole purpose of determining half of the transitional blended payment for site neutral payment rate cases during the transition period. (80 FR 24548 through 24549)

Comment: Some commenters requested that CMS provide more detail about how the GROUPER software will account for CCs and MCCs in grouping cases into one of the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs.

Response: When we proposed to adopt the severity-adjusted MS–DRGs (and by extension the MS–LTC–DRGs) as a replacement patient classification to the CMS DRG (and by extension the LTC–DRG) system, we present a detailed discussion on the development of the MCC, CC, and non-CC severity levels in the MS–DRGs and MS–LTC–DRGs (refer to the FY 2008 IPPS proposed rule (72 FR 24697 through 24706 and 24756 through 24757)). We also wish to point out that only two of the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs are grouped based on severity level. These are MS–LTC–DRG 945 (Rehabilitation with CC/MCC) and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). The grouping of LTCH cases into these MS–LTC–DRGs will be in accordance with our established method for grouping discharges into MS–LTC–DRGs when those MS–LTC–DRGs are subdivided based on severity level; that is, cases with at least one code that is on the CC or MCC list are assigned to the ''with CC/MCC'' MS–LTC–DRG (MS–LTC–DRG 945) by the GROUPER software and LTCH cases without a CC or an MCC are assigned to the ''without CC/MCC'' MS–LTC–DRG (MS–LTC–DRG 946) by the GROUPER software. Because the other 13 ''psychiatric or rehabilitation'' MS–LTC–DRGs (that is, MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, and 897), by definition, are not subdivided based on severity level under our established method for grouping discharges into MS–LTC–DRGs, the presence of code that is on the CC or MCC list will not impact the MS–LTC–DRG grouping for such cases. For a full discussion of our method of grouping under the MS–DRGs (and by extension, the MS–LTC–DRGs) based on severity level, we refer readers to the discussion of the development of the severity-adjust MS–DRGs in the FY 2008 IPPS proposed rule (72 FR 24697–24706).

Comment: Commenters generally supported the proposal to adopt the FY 2015 relative weights for the ''psychiatric or rehabilitation'' MS–LTC–DRGs. However, some commenters pointed out a technical error in Table 11 of the proposed rule. The commenters noted that although CMS stated in the preamble that for the 15 MS–LTC–DRGs CMS identified as ''psychiatric or rehabilitation,'' CMS proposed to adopt the FY 2015 relative weights (and average length of stay thresholds) for FY 2016 to pay for cases grouped to those MS–LTC–DRGs from LTCHs whose FY 2016 cost reporting periods had not yet begun and under the transitional blended payment rate. However, they added, the proposed FY 2016 relative weights (and proposed average length of stay thresholds) listed in Table 11 of the proposed rule were not the FY 2015 relative weights for those MS–LTC–DRGs established in the FY 2015 IPPS/LTCH PPS final rule.

Response: We appreciate the commenters' support of our proposal to adopt the FY 2015 relative weights for the ''psychiatric or rehabilitation'' MS–LTC–DRGs for FY 2016. The commenters correctly pointed out that Table 11 of the proposed rule contained an inadvertent technical error in the proposed FY 2016 relative weights (and average length of stay thresholds in that table) for the ''psychiatric or rehabilitation'' MS–LTC–DRGs. We are correcting that technical error in Table 11 of this final rule, and after consideration of public comments we are adopting our proposal to assign the FY 2016 MS–LTC–DRG relative weights (and average length of stay thresholds) for the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs the FY 2015 relative weights for those respective MS–LTC–DRGs without further change.

In summary, in this final rule, for FY 2016, as we proposed, we are establishing a relative weight (and average length of stay thresholds) equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs listed above (that is, 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 final rule and is available via the Internet on the CMS Web site, reflects the correction of the technical error discussed above.

Step 6—Adjust the FY 2016 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

As discussed earlier in this section, 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 could 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 will 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 FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments in this final rule, consistent with our historical methodology, as proposed, we combined 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 FY 2016 MS–LTC–DRG relative weights in this rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site.

Step 7— Calculate the FY 2016 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). Under the budget neutrality requirement at § 412.517(b), 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 updating the FY 2016 MS–LTC–DRG classifications and relative weights for LTCH PPS standard Federal payment rate payments based on the most recent available LTCH data for applicable LTCH cases, and applying a budget neutrality adjustment in determining the FY 2016 MS–LTC–DRG relative weights.

To ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), as proposed, we are continuing to use our established two-step budget neutrality methodology. As discussed previously in this section, this approach is consistent with our general policies regarding the continued use of our existing methodologies, as presented in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50175 through 50176).

In this final rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2016, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments were not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2016 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) We used the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2014 MedPAR file) and grouped them using the FY 2016 GROUPER (that is, Version 33 for FY 2016) and the recalibrated FY 2016 MS–LTC–DRG relative weights (determined in Steps 1 through 6 above) to calculate the average case-mix index; (1.b.) we grouped the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2015 GROUPER (Version 32) and FY 2015 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) we computed the ratio of these average case-mix indexes by dividing the average CMI for FY 2015 (determined in Step 1.b.) by the average case-mix index for FY 2016 (determined in Step 1.a.). As a result, in determining the MS–LTC–DRG relative weights for FY 2016, each recalibrated MS–LTC–DRG relative weight was multiplied by 1.27929 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces ''normalized relative weights.''

In the second step of our MS–LTC–DRG budget neutrality methodology, we calculated a second budget neutrality factor consisting of the ratio of estimated aggregate FY 2016 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. above) after reclassification and recalibration to estimated aggregate payments for FY 2015 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. above).

That is, for this final rule, for FY 2016, under the second step of the budget neutrality methodology, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) We simulated estimated total FY 2016 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the normalized relative weights for FY 2016 and GROUPER Version 33 (as described above); (2.b.) we simulated estimated total FY 2015 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2015 GROUPER (Version 32) and the FY 2015 MS–LTC–DRG relative weights in Table 11 of the FY 2015 IPPS/LTCH PPS final rule available on the Internet, as described in section VI. of the Addendum of that final rule (79 FR 5040 through 50402); and (2.c.) we 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 FY 2016 MS–LTC–DRG relative weights, each normalized relative weight was then multiplied by a budget neutrality factor of 1.0033952

(the value determined in Step 2.c.) in the second step of the budget neutrality methodology to determine the budget neutral FY 2016 relative weight for each MS–LTC–DRG.

Accordingly, in determining the FY 2016 MS–LTC–DRG relative weights in this final rule, consistent with our existing methodology, we applied a normalization factor of 1.27929 and a budget neutrality factor of 1.0033952 (computed as described above). Table 11, which is listed in section VI. of the Addendum to this rule and is available via the Internet on the CMS Web site, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)), and the ''IPPS Comparable Thresholds'' (used in determining SSO payments under § 412.529(c)(3)), for FY 2016 (and reflect both the normalization factor of 1.27929 and the budget neutrality factor of 1.0033952).

We did not receive any public comments on our proposed methodology for calculating the FY 2016 MS–LTC–DRG reclassification and recalibration budget neutrality factor, and we are adopting it as final without modification. We note that the public comments we received, our responses to those comments, and our finalized policy of applying a budget neutrality requirement as part of the annual recalibration of the MS–LTC–DRG relative weights for FY 2016 are presented in section VII.B.7.a. of this preamble of this final rule.

D. Changes to the LTCH PPS Standard Federal Payment Rates for FY 2016

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal prospective payment rates is set forth at § 412.515 through § 412.536. In this section, we discuss the factors that we used to update the LTCH PPS standard Federal payment rate for FY 2016, that is, effective for LTCH discharges occurring on or after October 1, 2015 through September 30, 2016. As previously discussed, under the dual rate LTCH PPS payment structure required by statute, we are establishing that, beginning with FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate will be 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 section VII.C. of the preamble of this final rule.)

For details on the development of the initial FY 2003 standard Federal rate, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS standard Federal rate 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); and FY 2015 IPPS/LTCH PPS final rule (79 FR 50176 through 50180).

In this FY 2016 final rule, we present our finalized policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2016, which includes the annual market basket update. Consistent with our historical practice of using the best data available, as proposed, we also used more recent data to determine the FY 2016 annual market basket update to the LTCH PPS standard Federal payment rate in this final rule.

The application of the update to the LTCH PPS standard Federal payment rate for FY 2016 is presented in section V.A. of the Addendum to this final rule. The components of the annual market basket update to the LTCH PPS standard Federal payment rate for FY 2016 are discussed below, including the reduction to the annual update for LTCHs that fail to submit quality reporting data for fiscal year FY 2016 as required by the statute (as discussed in section VII.D.2.c. of the preamble of this final rule). In addition, as discussed in section V.A. of the Addendum of this final rule, we made 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 2016 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4).

2. FY 2016 LTCH PPS Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for 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. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53468 through 53476), we adopted the newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. 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 53468).

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'' (which are discussed in more detail in section VII.C.2.b. of the preamble of this final rule.) 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. Revision of Certain Market Basket Updates as Required by the Affordable Care Act

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year through 2019, any annual update to the LTCH PPS standard Federal payment rate shall be reduced:

• For rate year 2010 through 2019, by the ''other adjustment'' specified in sections 1886(m)(3)(A)(ii) and (m)(4) of the Act; and

• For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as ''the multifactor productivity (MFP) adjustment'') described in section 1886(b)(3)(B)(xi)(II) 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.

Section 1886(b)(3)(B)(xi)(II) of the Act defines the MFP adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (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). Under our methodology, the end of the 10-year moving average of changes in the MFP coincides with the end of the appropriate FY update period. In addition, the MFP adjustment that is applied in determining any annual update to the LTCH PPS standard Federal payment rate is the same adjustment that is required to be applied in determining the applicable percentage increase under the IPPS under section 1886(b)(3)(B)(i) of the Act as they are both based on a fiscal year. We refer readers to section IV.A.1. of the preamble of this final rule for more information on the FY 2016 MFP adjustment.

c. Adjustment to the Annual Update 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, as added by section 3004(a) of the Affordable Care 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 § 412.523(c)(4) of the regulations. (As previously noted, although the language of section 3004(a) of the Affordable Care Act refers to years 2011 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, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.) The LTCH QRP, as required for FY 2014 and beyond 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 (§ 412.523(c)(4)(iii)). 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 (§ 412.523(c)(4)(ii)). We discuss the application of the 2.0 percentage point reduction under § 412.523(c)(4)(i) in our discussion of the annual market basket update to the LTCH PPS standard Federal payment rate for FY 2016 in section VII.D.2.e. of the preamble of this final rule. (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VII.C. of the preamble of this final rule.)

d. Market Basket Under the LTCH PPS for FY 2016

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we adopted a newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. The FY 2009-based LTCH-specific 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 FY 2009-based LTCH-specific market basket, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476).

For FY 2016, as proposed, we are continuing to use the FY 2009-based LTCH-specific market basket to update the LTCH PPS for FY 2016. We continue to believe that the FY 2009-based LTCH-specific market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted the FY 2009-based LTCH-specific market basket for use under the LTCH PPS in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476).

Comment: One commenter stated our proposal to use the FY 2009-based market basket update for FY 2016 is contradictory to our statements about the statutory change in the LTCH PPS payment structure, and the proposed rule contains language that states the FY 2009 LTCH-specific market basket is being used as the basis for FY 2016 update. The commenter referred our statement in the proposed rule that ''[w]e continue to believe that the FY 2009-based LTCH-specific market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted the FY 2009-based LTCH-specific market basket for use under the LTCH PPS. . . '' (80 FR 24552). The commenter believed the market basket should reflect the most currently available data to update the LTCH PPS standard Federal payment rate that will be used to pay LTCH cases that meet the criteria for exclusion from the site neutral payment rate.

Response: The proposed LTCH market basket update reflects the most recent forecast of the 2009-based LTCH-specific market basket for FY 2016. Specifically, the update reflects the projected growth in the relative input prices LTCHs are expected to encounter for the period of October 1, 2015 through September 30, 2016. The Medicare Cost Report used to determine the base year weights for the FY 2009-based LTCH-specific market basket was the most up-to date data available at the time of the rebasing in FY 2013. We have performed sensitivity analysis for various market baskets and found that the cost share weights do not change substantially from year to year. For this reason, it has been our historical practice to rebase the market baskets about every 4 years. As such, we disagree with the commenter's assertion that the FY 2009-based LTCH-specific market basket does not reflect the most currently available data to update the annual payment rates. Rather the FY 2009-based LTCH-specific market basket reflects IGI's latest forecast on price inflation at this time, and for these reasons we believe that it is appropriate to continue to use the FY 2009-based LTCH-specific market basket to update the LTCH PPS standard Federal payment rate for FY 2016.

After consideration of the public comments we received, we are finalizing our proposal to continue to use the FY 2009-based LTCH-specific market basket to update the LTCH PPS standard Federal payment rate for FY 2016.

e. Annual Market Basket Update for LTCHs for FY 2016

Consistent with our historical practice and our proposal, we estimate the market basket update and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's second quarter 2015 forecast, the FY 2016 full market basket estimate for the LTCH PPS using the FY 2009-based LTCH-specific market basket is 2.4 percent. The current estimate of the MFP adjustment for FY 2016 based on IGI's second quarter 2015 forecast is 0.5 percent, as discussed in section IV.A. of the preamble of this final rule. In addition, consistent with our historical practice, we are using a more recent estimate of the market basket and the MFP adjustment) to determine the FY 2016 market basket update and the MFP adjustment in this final rule.

For FY 2016, 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 reducing the full FY 2016 market basket update by the FY 2016 MFP adjustment. To determine the market basket update for LTCHs for FY 2016, as reduced by the MFP adjustment, consistent with our established methodology, we subtracted the FY 2016 MFP adjustment from the FY 2016 market basket update. 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 2016 be reduced by the ''other adjustment'' described in paragraph (4), which is 0.2 percentage point for FY 2016. Therefore, following application of the productivity adjustment, as proposed, we are further reducing the adjusted market basket update (that is, the full market basket increase less the 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 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 2016, section 1886(m)(5) of the Act requires that for LTCHs that do not submit quality reporting data as required under the LTCHQR Program, 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 update to the LTCH PPS standard Federal payment rate for FY 2016 for LTCHs that fail to submit quality reporting data under the LTCH QRP, the full LTCH PPS market basket increase estimate, subject to an adjustment based on changes in economy-wide productivity (''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, will also be further reduced by 2.0 percentage points.

In this final rule, in accordance with the statute, consistent with our proposal, we are reducing the FY 2016 full market basket estimate of 2.4 percent (based on IGI's second quarter 2015 forecast of the FY 2009-based LTCH-specific market basket) by the FY 2016 MFP adjustment of 0.5 percentage point (based on IGI's second quarter 2015 forecast). Following application of the productivity adjustment, the adjusted market basket update of 1.9 percent (2.4 percent minus 0.5 percentage point) was then reduced by 0.2 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(E) of the Act. Therefore, in this final rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are establishing an annual market basket update under to the LTCH PPS standard Federal payment rate for FY 2016 of 1.7 percent (that is, the most recent estimate of the LTCH PPS market basket update of 2.4 percent, less the MFP adjustment of 0.5 percentage point, and less the 0.2 percentage point required under section 1886(m)(4)(E) of the Act). Accordingly, consistent with our finalized policy, we are revising § 412.523(c)(3) by adding a new paragraph (xii), which specifies that the LTCH PPS standard Federal payment rate for FY 2016 is the LTCH PPS standard Federal payment rate for the previous LTCH PPS year updated by 1.7 percent, and as further adjusted, as appropriate, as described in § 412.523(d). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xi) in conjunction with § 412.523(c)(4), we are further reducing the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points in accordance with section 1886(m)(5) of the Act. Accordingly, consistent with our finalized policy, we are establishing an annual update to the LTCH PPS standard Federal payment rate of −0.3 percent (that is, 1.7 percent minus 2.0 percentage points) for FY 2016 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. As stated above, consistent with our historical practice, as proposed, we are using 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 2016 under § 412.523(c)(3)(xii) in this final rule. (We note that we also are adjusting the FY 2016 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 of this final rule).)

Comment: Based on its assessment of the adequacy of Medicare payments to LTCHs, which was presented in its March 2015 Report to the Congress, MedPAC concluded that no update to the LTCH PPS standard Federal payment rate for FY 2016 is warranted. MedPAC further stated that Medicare's current level of payments appears more than adequate to accommodate cost growth, even before any update, citing that Medicare margin for LTCHs for the past several years have exceeded five percent. For these reasons, MedPAC reiterated its recommendation that the Secretary eliminate the market basket update to the LTCH PPS standard Federal payment rate for FY 2016.

Response: We appreciate MedPAC's concerns about the necessity of a market basked update to the LTCH PPS standard Federal payment rate for FY 2016. However, as noted earlier, there is uncertainty surrounding of the LTCH patient universe under the new dual rate LTCH PPS payment structure, in particular the uncertainty as to what the costs of those cases will be during the transition to that revised system. Given this uncertainty, we do not believe that it is appropriate or prudent to eliminate the market basket update to the LTCH PPS standard Federal payment rate for FY 2016 at this time. For the reasons discussed above, we believe it is appropriate that the market basket update less the multi-factor productivity adjustment (and the ''other'' statutory adjustment) be applied in determining the LTCH PPS standard Federal payment rate for FY 2016 in order to keep pace with expected input price inflation. However, we will keep this recommendation in mind in developing

policies once we gain experience under the new system.

Comment: Some commenters requested that CMS clarify that the annual update established for IPPS excluded hospitals (that is, hospitals paid under the reasonable cost-based TEFRA payment system) for FY 2016, discussed in section VI of the Addendum to the proposed rule, is applicable to the target amount used to determine the LTCH PPS payment adjustment for ''subclause (II) LTCHs'' under existing § 412.526, and make any modifications to the regulations if needed.

Response: When we established the LTCH PPS payment adjustment for ''subclause (II) LTCHs'' at § 412.526, we established that for cost reporting periods beginning during FYs after FY 2015, the target amount (used to determine the adjusted payment for Medicare inpatient operating costs under reasonable cost-based reimbursement rules) 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). This provision is codified at § 412.526(c)(1)(ii) of the regulations, and, therefore, no modifications are needed to the existing regulations. However, in response to the commenters' request for clarification, we are taking the opportunity to specify that, for cost reporting periods beginning during FY 2016, the target amount for the payment adjustment for ''subclause (II) LTCHs'' is updated, consistent with the existing requirements of § 412.526(c)(1)(ii). As discussed in section IV. of the preamble of the proposed rule and the Addendum, the FY 2016 rate-of-increase percentage for updating the target amounts is equal to the estimated percentage increase in the FY 2016 IPPS operating market basket, in accordance with applicable regulations at § 413.40. Based on IHS Global Insight, Inc.'s 2015 second quarter forecast, with historical data through the 2015 first quarter, we estimate that the FY 2010-based IPPS operating market basket update for FY 2016 is 2.4 percent (that is, the estimate of the market basket rate of-increase). Therefore, the rate-of-increase percentage that will be applied to the FY 2015 target amounts in order to determine the FY 2016 target amounts for ''subclause (II) LTCHs'' under § 412.526(c)(1)(i) is 2.4 percent.

Comment: One commenter requested we rebase the LTCH PPS standard Federal payment rate (that is, recalculate the LTCH PPS standard Federal payment rate based on more recent cost report data). The commenter argued that LTCH cases that will receive an LTCH PPS standard Federal payment rate payment will be more resource intensive and thus warrant a higher base payment.

Response: While we consider this comment outside the scope of this proposed rule as we did not make any proposals to make such a recalculation of the LTCH PPS standard Federal rate beyond the annual market basked update (including any statutory adjustments), we do not believe that it is necessary or appropriate to rebase at this time. As we state several times throughout this preamble section, there is a good deal of uncertainty about the behavioral response of LTCHs to the new dual rate LTCH PPS payment structure as well as the nature of the future patient population in LTCHs. Furthermore, as we discuss in section VII.B.7.a. of this preamble, beginning with FY 2016, the annual update of the MS–LTC–DRG relative weights will be determined using only data from LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases), which will appropriately reflect the relative costliness and resource use of LTCH PPS standard Federal payment rate cases. For these reasons, we do not believe that rebasing is warranted at this time.

After consideration of the public comments we received, we are finalizing our of proposal to update the LTCH PPS standard Federal payment rate using the market basket update and the MFP adjustment based on IGI's forecast using the most recent available data (and the 'other' adjustments required by the statute). Accordingly, as stated above, consistent with our finalized policy, we are specifying at § 412.523(c)(3)(xii) that the LTCH PPS standard Federal payment rate for FY 2016 is the LTCH PPS standard Federal payment rate for the previous LTCH PPS year updated by 1.7 percent, and as further adjusted, as appropriate, as described in § 412.523(d).

E. Moratoria on the Establishment of LTCHs and LTCH Satellite Facilities and on the Increase in the Number of Beds in Existing LTCHs and LTCH Satellite Facilities

Section 1206(b)(2) of Public Law 113–67, as amended by section 112(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93), established ''new'' statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities and on the increase in the number of hospital beds in existing LTCHs and LTCH satellite facilities. For a discussion on our implementation of these moratoria, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50189 through 50193). Since the implementation of these LTCH PPS policy moratoria, we have been informed that some confusion may exist regarding the exceptions to the moratorium on the establishment of new LTCH and LTCH satellite facilities, as well as the application of the moratorium on an increase in the number of beds in existing LTCH and LTCH satellite facilities.

Under existing regulations at 42 CFR 412.23(e)(6), we specify that, to qualify for an exception under the moratorium to establish a new LTCH or LTCH satellite facility during the timeframe between April 1, 2014, and September 30, 2017, a hospital or entity must meet the following criteria:

- The hospital or entity must have begun its qualifying period for payment as an LTCH in accordance with § 412.23(e).
- The hospital or entity must have a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for an LTCH, and must have expended before April 1, 2014, at least 10 percent of the estimated cost of the project or, if less, $2,500,000.
- The hospital or entity must have obtained an approved certificate of need in a State where one is required.

As we stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24553), we believe that the existing regulation text regarding the moratorium on the establishment and classification of new LTCHs and LTCH satellite facilities could be misread as requiring fulfillment of all three conditions in order to qualify for an exception to the moratorium on the establishment of new LTCH and LTCH satellite facilities. This was not our intent, and we acknowledge that implementing the moratorium in that manner would have been directly contradictory to the statutory requirement. Technically, while we did not explicitly specify in the regulations text under § 412.23(e)(6) that only one of the listed criteria had to be met in order to qualify for an exception to the moratorium on the establishment of new LTCHs and LTCH satellite facilities (the language text states ''as applicable''), we clearly stated it in the preamble of the FY 2015 IPPS/LTCH PPS final rule. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50189 through 50193).) In addition, the requirement that one of the three exceptions had to be met in order to qualify for an

exception to the moratorium was also indicated in our proposal to implement the initial application of the moratorium during the FY 2009 rulemaking cycle. (We refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 29705).)

As we stated in the preamble of the FY 2015 IPPS/LTCH PPS final rule, the provisions in the new moratorium are nearly identical to the language in the prior ''expired'' moratorium under section 114(d) of MMSEA (Pub. L. 110–173). As also noted, the mechanics of exceptions to the new and expired moratoria on the establishment of new LTCHs and LTCH satellite facilities are analogous. Therefore, except as noted, to the extent that the new and expired moratoria were consistent, we proposed and adopted the identical implementation mechanisms. To minimize the confusion that may exist as a result of the existing regulations text, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24553), we proposed to revise the regulations under § 412.23(e)(6)(ii) to more clearly convey the established policy that only one of the statutory conditions needs to be met in order to qualify for the exception to the new moratorium on the establishment of new LTCH and LTCH satellite facilities.

We also have become aware of some confusion concerning what constitutes the ''estimated cost of the project'' with regard to the second exception. To alleviate confusion, we are further clarifying our longstanding policy on what constitutes the ''estimated cost of the project.'' In discussing this exception in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50189 through 50193), we noted that the ''cost of the project'' included the activities (plural) that were enumerated in the first prong of the exception. Those enumerated activities included ''the actual construction, renovation, lease, or demolition for a long-term care hospital.'' That is, our policy is that the sum total of any costs associated with any of the enumerated activities that comprised the project as a whole (with the project being the establishment of a new LTCH or a new LTCH satellite facility) would be considered in determining whether the facility met the amount specified in the statute. In using an ''or'' in this list of activities, we intended to acknowledge that any one project may or may not include every element listed (for example, new construction may not include any demolition), but if it does include an element, our policy is that the cost of that element and the costs of any other of the listed elements in the project are to be summed to determine the total cost of the project. Therefore, under our longstanding policy, when determining whether 10 percent of the estimated cost of the project had been expended prior to the start of the moratorium, the ''project'' is the establishment of a new LTCH or LTCH satellite facility, not any one element that, when combined with other elements listed in the first prong, would lead to the establishment of the LTCH or LTCH satellite facility. For example, if an entity has expended 10 percent of the costs of demolition, but that amount is less than both 10 percent of the estimated cost of the project, and less than the $2,500,000.00 ceiling amount, the entity would not qualify for this exception to the moratorium.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24554), we also noted that we were taking that opportunity to provide additional clarification on our policy concerning the moratorium on increases in the number of beds in existing LTCH and LTCH satellite facilities. As we noted in the FY 2015 IPPS/LTCH PPS final rule, while the expired moratorium specifically included an exception to the moratorium on the increase in the number of beds in existing LTCHs and LTCH satellite facilities, the new moratorium under section 1206(b)(2)(B) of Public Law 113–67 expressly noted that the exceptions to the expired moratoria would not apply under the ''new'' moratoria. Further amendments made by section 112(b) of Public Law 113–93, created certain exceptions, but did not retract the prior statement regarding the express omission of any exceptions (79 FR 50189 through 50193). As the further amendments only provided exception to the moratorium on establishing new satellites, the express omission of any exceptions to the new moratorium on increasing the number of beds in an existing LTCH or LTCH satellite facility remained in place. As such, an LTCH may not increase the total number of Medicare certified beds beyond the number that existed prior to April 1, 2014, including when an existing LTCH meets one of the exceptions to the moratorium on the establishment of a new LTCH satellite facility. An LTCH satellite facility's beds historically have been, and continue to be, counted as the LTCH's beds. Therefore, under our existing regulation at § 412.23(e)(7)(iii), an existing LTCH cannot, through meeting the criteria for an exception to the new moratorium on the establishment of a new LTCH satellite facility, increase its total number of Medicare certified beds by establishing any number beds at the new LTCH satellite facility that would result in the total number of Medicare certified beds in that LTCH exceeding what existed prior to April 1, 2014. That is, if an existing LTCH meets one of the statutory exceptions for new satellite facilities and opens a new LTCH satellite facility during the moratorium, that new LTCH satellite facility's beds must come from the movement of beds in existence prior to April 1, 2014, from other locations of the existing LTCH to the new LTCH satellite facility. This requirement also applies to any remote locations that may be established by an existing LTCH during the moratorium on new beds.

Comment: Several commenters expressed concern with CMS' articulation of the existing policy. The commenters believed that CMS was proposing to change policy, rather than clarifying existing policy. The commenters urged CMS to adopt a final policy expressly inverse to its clarification.

Response: We disagree with any assertion that the clarification in the proposed rule represents a change in policy. When we implemented the current moratorium in the FY 2015 IPPS/LTCH PPS final rule, we stated that an existing LTCH may not increase the number of its hospital beds. This policy was not subject to any exceptions (79 FR 50190). We discussed in that final rule, in response to several comments received that urged us to create a regulatory exception to the bed moratorium, that we did not believe an exception was warranted and, therefore, did not establish one. We believe that our clear statement in the FY 2015 final rule, our decision not to provide for exceptions to the bed moratorium, and our longstanding policy to count a satellite facility's beds as an LTCH's beds were clear articulations of our policy. Nonetheless, as we were later informed that there was confusion regarding the moratorium, in the FY 2016 IPPS/LTCH PPS proposed rule, we reiterated our existing policy to alleviate that confusion.

In summary, without exception, an LTCH may not increase the total number of Medicare certified beds beyond the number that existed prior to April 1, 2014. The number of Medicare certified beds in an LTCH includes beds in all locations, including, as applicable, satellite facilities.

F. Changes to Average Length of Stay Criterion Under Public Law 113–67 (§ 412.23)

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24554), we proposed to revise § 412.23 to bring it into conformance with the self-

implementing statutory changes under section 1206(a)(3) of Public Law 113–67 regarding how the average length of stay for an LTCH is to be calculated. As required by section 1861(ccc) of the Act, in order for a hospital to be classified as an LTCH, it must maintain an average length of stay of greater than 25 days as calculated by the Secretary (or meet the requirements of clause (II) of section 1886(d)(1)(B)(iv) of the Act). Prior to the statutory change in Public Law 113–67, the Medicare average length of stay was calculated, in accordance with § 412.23(e)(3) of the regulations, by dividing the total number of covered and noncovered Medicare inpatient days by the total number of Medicare discharges. This calculation included Medicare inpatient days and discharges that were paid under a Medicare Advantage (MA) plan. (For a full discussion of the inclusion of MA days in the average length of stay calculation, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51774).)

Section 1206(a)(3)(A) of Public Law 113–67 specified that, in general, for discharges occurring in cost reporting periods beginning on or after October 1, 2015, applicable total Medicare inpatient days and discharges that are paid at the site neutral payment rate (discussed in section VII.B. of the preamble of the proposed rule and this final rule with comment period), or for which payments are made under an MA plan, are to be excluded from the calculation of an LTCH's average length of stay. Section 1206(a)(3)(B) of Public Law 113–67 further required that this exclusion of site neutral and MA days would not apply to an LTCH that was classified as a ''subsection (d) hospital'' as of December 10, 2013. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule, we proposed to amend § 423.23 to conform with this self-implementing statutory exclusion and the self-implementing statutory exception to the exclusion, by revising paragraphs (e)(3)(ii) through (e)(3)(v), adding a new paragraph (e)(3)(vi), and revising the introductory text of paragraph (e)(6)(ii).

We did not receive any public comments on our proposals. However, upon further consideration, we realized that section 112(c)(2) of Public Law 113–93 altered the ''subsection (d) hospital'' language established by section 1206(a)(3)(B) of Public Law 113–67 to ''long-term care hospital.'' That is, section 112(c)(2) of Public Law 113–93 removed the phrase ''subsection (d) hospital'' in the provision regarding entities ''classified as a subsection (d) hospital as of December 10, 2013'' and in its place inserted ''long-term care hospital'', resulting in the combined statutory mandates providing ''classified as a long-term care hospital as of December 10, 2013''. While we initially mistakenly thought of this legislative language change as a technical change, we now recognize its substantive effect. As the change is statutorily mandated and self-implementing, we are making conforming changes to what we proposed in paragraph (e)(3)(vi) of § 412.23 (which specified that the provisions do not apply to a hospital classified as a ''subsection (d) hospital'' as of December 10, 2013). As the statute does not set forth any discretion on this provision, and as commenters did not object to the other content of our proposed text for § 412.23, using the authority noted below, we are waiving notice-and-comment rulemaking for this change (replacing ''subsection (d) hospital'' with ''long-term care hospital'') in our proposed rule's text, finalizing that change, and otherwise finalizing the remaining proposed regulation text changes in § 412.23 without modification.

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect. We can waive this procedure, however, if we find good cause that notice-and-comment procedures are impracticable, unnecessary, or contrary to the public interest and we incorporate a statement of finding and its reasons in the rule (5 U.S.C. 553(b)(B)). To that end, we find that it is unnecessary to undertake notice-and-comment rulemaking for the changes to the average length of stay calculation at 42 CFR 412.23(e)(3)(vi) (governing the exclusion of site neutral stays and MA days from the calculation) because those changes are statutorily required modifications to how the average length of stay is to be calculated. We find that notice-and-comment rulemaking is unnecessary to implement these statutory changes to the average length of stay calculation because they are self-implementing provisions of law, not requiring the exercise of any discretion on the part of the Secretary. As such, the changes in this final rule to the average length of stay calculation in § 412.23(e)(3)(vi) need not be published in a proposed rule prior to publication in this final rule, as such publication is unnecessary in the absence of any discretion regarding this aspect of the average length of stay calculation. Therefore, we find good cause to waive notice-and-comment procedures concerning the average length of stay calculation at § 412.23 (e)(3)(vi).

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. This effort is supported by the adoption of widely agreed-upon quality measures. We have worked with relevant stakeholders to define quality measures for most settings and to measure various aspects of care for most Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, care coordination, and improving patient outcomes.

We have implemented quality reporting programs for multiple care settings, including:

- Hospital inpatient services under the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program);
- Hospital outpatient services under the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP));
- Care furnished by physicians and other eligible professionals under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (also referred to as the LTCHQR Program);
- PPS-exempt cancer hospitals under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program;
- Home health agencies under the home health quality reporting program (HH QRP); and,
- Hospice facilities under the Hospice Quality Reporting Program.

We have also implemented the End-Stage Renal Disease Quality Incentive Program and Hospital VBP Program (described further below) that link payment to performance.

In implementing the Hospital IQR Program and other quality reporting

programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the reporting burden on providers will be reduced. As appropriate, we will consider the adoption of clinical quality measures with electronic specifications so that the electronic collection of performance information is a seamless component of care delivery. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, adoption of measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and reporting burden to hospitals. We believe that in the near future, collection and reporting of data elements through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that hospitals will be able to switch primarily to EHR-based data reporting for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We also have implemented a Hospital VBP Program under section 1886(o) of the Act, described in the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We most recently adopted additional policies for the Hospital VBP Program in section IV.I. of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087). Under the Hospital VBP Program, hospitals receive value-based incentive payments based on their performance with respect to performance standards for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures (other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

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 specified under the Hospital IQR Program, these two programs are linked and the reporting infrastructure for the programs overlap. We view 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. Value-based purchasing is an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations.

We also view the Hospital-Acquired Condition (HAC) payment adjustment program authorized by section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, and the Hospital VBP Program, as related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance on a wide variety of measures, while the HAC Reduction Program creates a payment adjustment resulting in payment reductions for poorly performing hospitals based on their rates of HACs.

In the preamble of the FY 2016 IPPS/LTCH PPS proposed rule, we proposed changes to the following Medicare quality reporting systems:

- In section VIII.A. (80 FR 24555 through 24590), the Hospital IQR Program.
- In section VIII.B. (80 FR 24590 through 24595), the PCHQR Program.
- In section VIII.C. (80 FR 24595 through 24611), the LTCH QRP.

In addition, in section VIII.D. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24611 through 24615), we proposed changes to the Medicare EHR Incentive Program for eligible hospitals and CAHs.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of the Hospital IQR Program

We refer readers to the FY 2010 IPPS/RY 2010 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) for the measures we have adopted for the Hospital IQR measure set through the FY 2017 payment determination and subsequent years.

b. Maintenance of Technical Specifications for Quality Measures

The technical specifications for the Hospital IQR Program measures, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission (TJC) Specifications Manual for National Hospital Quality Measures (Specifications Manual). This Specifications Manual is posted on the QualityNet Web site 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 measures. These semiannual updates are accompanied by notifications to users, providing sufficient time between the change and the effective date in order to allow users to incorporate changes and updates to the specifications into data collection systems.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS *Quality Assurance Guidelines* manual available at the HCAHPS Web site, *http://www.hcahpsonline.org*. We maintain the HCAHPS technical specifications by updating the HCAHPS *Quality Assurance Guidelines* manual annually, and include detailed instructions on survey implementation, data collection, data submission and other relevant topics. As necessary, HCAHPS Bulletins are issued to provide notice of changes and updates to technical specifications in HCAHPS data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are endorsed by the National Quality Forum (NQF). As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every three years. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50202 through 50203) for additional detail on the measure maintenance process.

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 the

subregulatory process to make non-substantive updates to measures used for the Hospital IQR Program. We recognize that some changes made to NQF-endorsed measures undergoing maintenance review are substantive in nature and might not be appropriate for adoption using a subregulatory process. We will continue to use rulemaking to adopt substantive updates made to measures we have adopted for the Hospital IQR Program.

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 submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50776 through 50778) for a more detailed discussion about public display of quality measures. We did not propose to change our current policy of reporting data from the Hospital IQR Program as soon as it is feasible on CMS Web sites such as the *Hospital Compare* Web site *http://www.medicare.gov/hospitalcompareand/* or the interactive *https://data.medicare.gov* Web site, after a preview period.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. For more information on measures reported to *Hospital Compare,* we refer readers to the Web site at: *http://www.medicare.gov/hospitalcompare*. Other information not reported to *Hospital Compare* may be made available on other CMS Web sites such as *http://www.cms.hhs.gov/HospitalQualityInits/* or *https://data.medicare.gov*.

2. Process for Retaining 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. When we adopt measures for the Hospital IQR Program beginning with a particular payment determination, these measures are automatically adopted for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24556), we did not propose any changes to our policy for retaining previously adopted measures for subsequent payment determinations.

3. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures From the Hospital IQR Program

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 also take into account the views of the Measure Applications Partnership (MAP) when determining when a measure should be removed, and we strive to eliminate redundancy of similar measures (77 FR 53505 through 53506). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we also finalized our proposal to clarify the criteria for determining when a measure is ''topped out.'' In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24556), we did not propose any changes to the two criteria that we use to determine whether or not a measure is ''topped out.''

We use these previously adopted measure removal criteria to help evaluate when we should propose a measure for removal. However, we continue to believe that there are circumstances in which a measure that meets criteria for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure. Therefore, because of the continued need to balance benefits and drawbacks as well as our desire to increase transparency, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24556 through 24557), we proposed additional factors to consider for measure removal and also include factors to consider in order to retain measures.

Specifically, we proposed to take into consideration the following additional factor in determining whether a measure should be removed:

- Feasibility to implement the measure specifications.

In addition, we proposed to remove one of the factors (''Availability of alternative measures with a stronger relationship to patient outcomes'') we take into consideration when determining whether to remove measures, because it is duplicates another factor (''The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic'').

We also proposed to take into consideration the following factors in determining whether a measure should be retained:

- Measure aligns with National Quality Strategy or CMS Quality Strategy goals;
- Measure aligns with other CMS programs, including other quality reporting programs, or the EHR Incentive Program; and
- Measure supports efforts to move facilities towards reporting electronic measures

For example, we may consider retaining a measure that is statistically ''topped-out'' in order to align with the Medicare EHR Incentive Program. Below is a table of newly proposed and previously adopted factors that we would take into consideration in removing or retaining measures:

FACTORS CMS CONSIDERS IN REMOVING OR RETAINING MEASURES

Measure Removal Factors
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).
2. A measure does not align with current clinical guidelines or practice.
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).
4. Performance or improvement on a measure does not result in better patient outcomes.
5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

FACTORS CMS CONSIDERS IN REMOVING OR RETAINING MEASURES—Continued

6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
7. It is not feasible to implement the measure specifications.*
''Topped-Out'' Criteria
1. • Statistically indistinguishable performance at the 75th and 90th percentiles; and • Truncated coefficient of variation ≤ 0.10.
Measure Retention Factors
1. Measure aligns with other CMS and HHS policy goals.*
2. Measure aligns with other CMS programs, including other quality reporting programs, or the EHR Incentive Program.
3. Measure supports efforts to move facilities towards reporting electronic measures.

* Consideration proposed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24556 through 24557).

We note that these removal/retention factors continue to be considerations taken into account when deciding whether or not to remove measures; but they are not firm requirements.

We invited public comments on our proposal.

Comment: Several commenters supported the considerations in removing/retaining quality measures and noted their appreciation for our efforts to align with other programs as well as the National Quality Strategy or CMS Quality Strategy goals, and to consider the feasibility of data collection and reporting. Several commenters specifically noted their support for CMS' efforts to transition to electronic clinical quality measures.

Response: We thank the commenters for their support.

Comment: Several commenters supported the addition of a measure retention criterion stating ''Measure supports efforts to move facilities towards reporting electronic measures.''

Response: We thank the commenters for their support.

Comment: Some commenters requested more detail on the measure removal criterion: ''feasibility to implement the measure specifications.'' A few commenters recommended that this measure removal criterion should include considerations of the difficulty of collection experienced by providers. The commenters also recommended that the assessment should evaluate the impact on clinical workflow, the degree of completeness, and the ease of related data collection requirements assumed to be derived from clinical workflow.

Response: In considering the ''feasibility to implement the measure specifications'' as proposed, we consider both our ability to receive the necessary data, as well as hospitals' ability to collect the measure data. Accordingly, when considering this measure removal criterion, we account for data collection challenges, including, but not limited to clinical workflow, the degree of completeness, and the ease of related data collection requirements, experienced by hospitals and providers.

Comment: One commenter encouraged CMS to consider approaches to improve hospital performance on measures that are slow to meet the ''topped-out'' criteria. Specifically, the commenter indicated that there is a need to put additional focus on the process measures that are tied to high quality data within IQR in order to support improvement of hospital quality and patient outcomes.

Response: We thank the commenter for its suggestion and note that we generally retain measures until they either become ''topped-out'' or meet one of the other measure removal criteria. We believe that the inclusion of these measures, whether they are process or outcomes measures, in the Hospital IQR Program will drive hospitals to improve performance. However, we will take the commenter's suggestion to put additional focus on process measures tied to high quality data under advisement for our plans for education and outreach on the Hospital IQR Program.

Comment: A few commenters opposed the proposed criterion ''measure aligns with other CMS and HHS policy goals'' as a factor to be considered for measure retention, noting that there may be reasons to remove a measure from one program, even though it is still appropriate in another.

Response: We would like to clarify that when we consider whether or not a ''measure aligns with other CMS and HHS policy goals,'' we evaluate whether a measure supports the CMS Quality Strategy goals or the National Quality Strategy, instead of alignment with other quality reporting programs. We are however, finalizing another criterion that allows retention of a measure that aligns with other quality reporting programs, such as the EHR Incentive Program, in order to enable hospitals to rely on the same measures to meet the requirements of multiple programs.

Comment: A few commenters opposed the addition of the measure removal criterion ''measure supports efforts to move facilities towards reporting electronic measures.'' Some commenters suggested that a measure-by-measure approach to accelerating/encouraging electronic reporting is not adequate.

Response: We clarify that we have added this criterion in acknowledgement that there may be instances when we may consider retaining an electronic version of a measure that is statistically ''topped out'' in its chart-abstracted mode specifically to align with the EHR Incentive Program. Accordingly, we make every effort to ensure an aligned set of electronic clinical quality measures across the Hospital IQR Program and the EHR Incentive Program.

Comment: One commenter supported the removal of topped out measures, noting that they provide little room for improvement, but recommended the creation of a system to monitor performance on retired measures to ensure that quality gains are sustained.

Response: We thank the commenter for its support and will take its suggestion under consideration.

After consideration of the public comments we received, we are finalizing factors that we would take into consideration in removing or retaining measures as proposed. Specifically, we are finalizing: (1) The addition of the removal factor ''feasibility to implement the measure specifications;'' (2) the removal of the factor ''availability of alternative measures with a stronger relationship to patient outcomes;'' and (3) the addition of the retention factors ''measure aligns with National Quality Strategy or CMS Quality Strategy goals,'' ''measure aligns with other CMS programs, including other quality reporting programs, or the

EHR Incentive Program,'' and ''measure supports efforts to move facilities towards reporting electronic measures.''

b. Removal of Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24557 through 24560), we proposed to remove the following nine measures, either in their entirety or just the chart abstracted form, from the Hospital IQR Program measure set for the FY 2018 payment determination and subsequent years: STK–01: Venous Thromboembolism (VTE) Prophylaxis (NQF #0434), STK–06: Discharged on Statin Medication (NQF #0439), STK–08: Stroke Education (NQF endorsement removed), VTE–1: Venous Thromboembolism Prophylaxis (NQF #0371), VTE–2: Intensive Care Unit Venous Thromboembolism Prophylaxis (NQF #0372), VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373), IMM–1: Pneumococcal Immunization (NQF #1653), AMI–7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival (NQF #0164), and SCIP-Inf-4: Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300).

(1) STK–01, STK–06, STK–08, VTE–1, VTE–2, and VTE–3

We proposed to remove the chart-abstracted versions of STK–01, STK–06, STK–08, VTE–1, VTE–2, and VTE–3 because these measures are ''topped-out.'' However, we proposed to retain STK–06, STK–08, VTE–1, VTE–2, and VTE–3 as electronic clinical quality measures for the FY 2018 payment determination and subsequent years. As we state in section VIII.A.3.a. of the preamble of this final rule, in our discussion of factors we consider in removing or retaining a measure, ''topped-out'' status is only one of many factors, which we consider.

In balancing the benefits and disadvantages of removing or retaining a measure, we believe that the benefits of retaining the electronic versions of these measures outweigh the possible disadvantages. Specifically, we believe that while these measures are statistically ''topped-out,'' retaining the electronic versions of the measures is beneficial because they align the Hospital IQR Program with the Medicare EHR Incentive Program. In addition, retaining the electronic version of the measures would allow us to monitor the effectiveness of measure reporting by EHRs and help to familiarize hospitals with reporting electronically specified measures to CMS under the Hospital IQR Program.

Our data show that the electronically specified versions of these measures are reported with non-zero values by as many as 2,864 hospitals attesting under 2014 Meaningful Use and that hospitals report on the full range of available electronic clinical quality measures. Accordingly, we know that EHRs are certified to these measures, and that hospitals do indeed report them. The available data suggest that retaining STK–06, STK–08, VTE–1, VTE–2, and VTE–3 as electronic clinical quality measures furthers CMS' high priority goal to enable the electronic reporting of quality data and to align the Hospital IQR and EHR Incentive Programs.

We also believe that reporting electronic clinical quality measures presents minimal burden on hospitals as compared to their chart-abstracted equivalents and that retaining the electronically specified versions of these measures is appropriate until we fully understand the differences between the chart-abstracted and electronic versions of quality measures. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50808) we stated that we do not believe that the measures, in their electronically specified form, are substantively different than their chart-abstracted form, although we recognized that the EHR-based extraction methodology is different from the chart-abstraction data collection methodology.

However, CMS now recognizes that although the intent of a measure is the same whether it is reported via chart-abstraction or electronically, the submission modes are not the same and measure rates may be different.

As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we have only heard anecdotal comments about actual performance level differences between the two modes of collection. We do not have sufficient data to be able to confirm these comments, but in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50273), we finalized a proposal to conduct a validation pilot test for electronically specified measures, which we intend to complete in 2015. The results of this pilot are not yet available. As we have stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53555), determining the equivalence of electronic clinical quality measures and chart-abstracted measures would require extensive testing given that the data for the Hospital IQR Program supports public reporting for both the Hospital IQR and Hospital VBP Programs. Due to the reasons described above, we believe it is appropriate to retain the electronically specified version of these five measures at this time.

We invited public comment on our proposals.

Comment: Several commenters supported the proposal to remove the chart-abstracted versions of the nine indicated measures in the Hospital IQR Program and retaining them as electronic clinical quality measures. The commenters noted that the removal of these measures reduces administrative burdens on hospitals.

Response: We thank the commenters for their support.

Comment: Several commenters supported the proposal to remove the six ''topped-out'' measures and to retain five of the measures as electronic clinical quality measures, noting their support of the transition from manually abstracted measures to the electronic versions.

Response: We thank the commenters for their support.

Comment: One commenter supported the proposed removal of STK–1 in its entirety and the removal of the chart abstracted versions of STK–06, STK–08, VTE–1, VTE–2, and VTE–3. However, the commenter suggested that a future policy should be adopted for coordinating measure removal and the maintenance of the National Hospital Inpatient Quality Measures (NHIQM) specifications such that vendors have adequate time to accommodate the changes.[115]

Response: We thank the commenter for its support. We also note that we consider a number of guidelines and considerations, outlined above, when determining whether to remove or retain measures from the Hospital IQR Program measure set. Considerations include the NHIQM specifications,[116] which represent the result of efforts by CMS and The Joint Commission to achieve consistency among common national hospital performance measures and to share a single set of common documentation. In addition, we note that the retention of the electronic versions of STK–06, STK–08, VTE–1, VTE–2, and VTE–3 does not introduce new specifications for vendors to accommodate, as these measures have been in the Hospital IQR Program in previous years, thus negating the

[115] TJC. Specifications Manual for National Hospital Inpatient Quality Measures. Retrieved from: *http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx.*

[116] TJC. Specifications Manual for National Hospital Inpatient Quality Measures. Retrieved from: *http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx.*

concern of vendors needing adequate time to accommodate changes.

Comment: One commenter noted that it is currently developing guidelines for VTE that can inform the development of future measures.

Response: We thank the commenter for sharing that they are working in this area and look forward to the insight the guidelines can provide for the development of VTE measures.

Comment: One commenter expressed concern that the proposed removal of the chart-abstracted version of measures will reduce quality standards and recommends that no chart-abstracted measures be replaced until such time that electronic clinical quality measures can be submitted and reported with high fidelity, accuracy and quality threshold requirements. The commenter also expressed concern that as chart-abstracted measures are removed from the Hospital IQR Program, abstraction and submission vendors may remove functionality from quality measurement submission software, impeding performance tracking, limiting hospitals' ability to track both the chart-abstracted and electronic version of such measures in parallel, and reducing the number of measurements that can be used to implement new payment models within the private sector.

Some commenters recommended that the chart-abstracted versions of ''topped-out'' measures be retained and requested that both electronic clinical quality measure and chart-abstracted measure data be published, to enable comparisons.

Response: We note that the five measures that we proposed for removal in their chart-abstracted form but retained the electronic versions of met our ''topped-out'' criteria as specified in FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) where the formulas are discussed. Accordingly, we believe that the removal of these measures is appropriate and that the removal of the functionality to capture the chart-abstracted versions of these measures will not negatively affect quality.

In addition, we believe that retaining the electronic versions of six measures (STK–06, STK–08, VTE–1, VTE–2, VTE–3, and AMI–7a) is appropriate because they align the Hospital IQR Program with the Medicare EHR Incentive Program, allow us to monitor the effectiveness of measure reporting by EHRs, and help to familiarize hospitals with reporting electronically specified measures to CMS. We also note that a validation pilot test for electronically specified measures is being completed in 2015 in order to ensure that electronic measures can be submitted and reported with high fidelity, accuracy and quality threshold requirements. Finally, we note that the Hospital IQR Program measure set includes six measures (ED–1, ED–2, STK 04, VTE–5, VTE–6, and PC–01) which have the capability to be reported both via chart-abstraction and electronically. We refer readers to section VIII.8.b. of the preamble of this final rule below in which we discuss our modified policies finalized, including that these measures are required via chart-abstraction and data will be posted to *Hospital Compare*. Hospitals may submit these measures via both methods. This information may allow us to compare the chart-abstracted and electronic versions of measure data, in order to confirm variability between data sources.

Comment: Several commenters expressed continuing concern regarding the removal of measures that are deemed ''topped-out,'' noting their belief that the removal of these measures could result in unintended adverse consequences, as well as signal a general disinterest in this aspect of care on the part of CMS. The commenters recommended that CMS ensure that the proposed removal would not cause any gaps in care. A few commenters recommended that sample ''topped-out'' measures be audited periodically to ensure satisfactory performance, noting that periodic auditing could detect reductions on quality of care.

Response: We believe that removing measures meeting the ''topped-out'' criteria will not negatively affect quality, because by definition, performance on these measures is adequately high. In addition, we believe that the addition of measure retention criteria, described above, signals our intent to retain measures that address high priority aspects of care, even if those measures are ''topped-out.'' Finally, we want to thank the commenters for their suggestion that we consider auditing ''topped-out'' measures.

Comment: One commenter supported the proposed removal of the STK measures. However, the commenter was concerned that the remaining STK–04 measure will be ineffectual, as it is a measure with low volume.

Response: We thank the commenter for its support of the proposed removal of the STK measures in their chart-abstracted forms. We believe that STK–04 should remain in the program in its chart-abstracted form, because based on our calculations in accordance with our ''topped out'' policy, it does not fall under this category. Due to this, we believe there is room for improvement in performance. Over 900 hospitals submitted data on this measure in CY 2014 for the FY 2016 payment determination, however, we will re-evaluate the measure for next year's proposed rule.

Comment: Several commenters supported the removal of the ''topped-out'' measures, but questioned the value of retaining the electronic versions of those measures. Specifically, the commenters expressed concern that the retention of the electronic versions of these measures, which were developed for chart abstraction and translated to electronic measures, will delay movement to measures that were developed using EHRs. One commenter also noted concern that this policy requires inappropriate use of resources and has no impact on quality.

Response: We do not believe that these measures, in their electronically specified form, are substantively different than their chart-abstracted form, despite our recognition that: (1) The EHR-based extraction methodology is different from the chart abstraction data collection methodology, and (2) measure rates may vary depending on methodology. We believe that retaining the electronic versions of these measures is beneficial, because it allows us to align the Hospital IQR Program with the Medicare EHR Incentive Program. We refer readers to section VIII.8.b. of the preamble of this final rule where we discuss our finalized modified policy. We are retaining a variety of electronic clinical quality measures in order to ensure that hospitals have flexibility and choice in determining which electronic measures to report. In addition, retaining the electronic versions of measures does not detract from developing new measures based on data elements readily available in EHRs.

In regards to the comment that electronic clinical quality measure reporting requires an inappropriate use of resources, we disagree, and note that a movement towards the use of electronic data is a national priority, as evidenced by the HITECH act and Meaningful Use program requirements. We believe that the collection of electronic clinical quality measure data will enable hospitals to efficiently capture and calculate quality data that can be used to address quality at the point of care and track improvements over time.

We will make note of the issues raised in the comments received for next year's proposed rule, when we may consider removing additional electronic clinical

quality measures from the Hospital IQR Program, possibly including:

- VTE–3 VTE Patients with Anticoagulation Overlap Therapy (NQF #0373);
- VTE–4 VTE Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram) (NQF N/A);
- VTE–5 VTE Discharge Instructions (NQF N/A);
- VTE–6 Incidence of Potentially Preventable VTE (NQF N/A);
- PN–6 Initial Antibiotic Selection for Community- Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147);
- Healthy Term Newborn (NQF #0716);
- AMI–7a Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival (NQF #0164);
- SCIP–INF–9 Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero (NQF N/A);
- CAC–3 Home Management Plan of Care (HMPC) Document Given to Patient/Caregiver (NQF N/A);
- AMI–2-Aspirin Prescribed at Discharge for AMI (NQF N/A);
- AMI–10 Statin Prescribed at Discharge (NQF N/A);
- SCIP–INF–1a Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527); and,
- SCIP–INF–2 Prophylactic Antibiotic Selection for Surgical Patients.

After consideration of the public comments we received, we are finalizing our proposal to remove the chart-abstracted versions of STK–01, STK–06, STK–08, VTE–1, VTE–2, and VTE–3, but also retain STK–06, STK–08, VTE–1, VTE–2, and VTE–3 as electronic clinical quality measures for the FY 2018 payment determination and subsequent years as proposed.

(2) IMM–2 Influenza Immunization (NQF #1659)

One additional measure, IMM–2, has been determined to be statistically ''topped-out;'' however, after considering the benefits and disadvantages of removing or retaining this measure, we are retaining this measure in the Hospital IQR Program measure set for the FY 2018 payment determination and subsequent years, because the benefits outweigh the disadvantages. One of the factors that we consider when determining whether to remove or retain a measure is whether a measure aligns with National Quality Strategy (NQS) or CMS Quality Strategy goals. Currently, IMM–2 is the only Hospital IQR Program measure to address the Best Practices to Enable Healthy Living NQS Priority and CMS Quality Strategy goal. In addition, IMM–2 supports the NQS priorities and CMS Quality Strategy goals to promote effective interventions to prevent and reduce the leading causes of mortality.[117]

Comment: Several commenters supported the retention of the IMM–2 Influenza Immunization measure in the Hospital IQR Program, noting that the measure plays a critical role in CMS' Best Practices to Enable Healthy Living NQS Priority and CMS Quality Strategy goal.

Response: We thank the commenters for their support.

Comment: A few commenters opposed CMS' proposal to retain IMM–2 despite its ''topped-out'' status, citing the burden associated with reporting the measure and the little benefit and value they believe retention will add.

Response: While we recognize that the IMM–2 measure has been statistically deemed ''topped-out,'' it is the only Hospital IQR Program measure to address the Best Practices to Enable Healthy Living NQS Priority and CMS Quality Strategy goal. In addition, IMM–2 supports other NQS priorities and CMS Quality Strategy goals to promote effective interventions to prevent and reduce the leading causes of mortality. In accordance with the measure removal and retention criteria discussed in section VIII.8.b of the preamble of this rule, we believe that the value of retaining this measure outweighs the burden associated with collection as well as the ''topped-out'' status. Accordingly, we believe that the measure is valuable in promoting quality and that this measure adds value to the Hospital IQR Program measure set.

After consideration of the public comments we received, we are finalizing our policy to retain IMM–2 Influenza Immunization (NQF #1659) as proposed.

(3) Removal of Immunization 1 (IMM–1) Pneumococcal Immunization (NQF #1653)

We adopted the IMM–1 Pneumococcal Immunization measure (NQF #1653) for the FY 2014 payment determination and subsequent years with data collection beginning with January 1, 2012 discharges (75 FR 50211). In October 2012, subsequent to the beginning of IMM–1 data collection on January 1, 2012, the Advisory Committee on Immunization Practices (ACIP) published new guidelines on pneumococcal vaccination.[118] With the publication of the new ACIP guidelines, IMM–1, as specified in the Hospital IQR Program, was no longer compliant with current clinical guidelines.

As part of our efforts to re-specify IMM–1 to account for the many potential scenarios that must be considered when determining if pneumococcal vaccination is appropriate, we determined that it was not feasible to implement the measure specifications that incorporated the new guidelines given their complexity.

Specifically, the October 2012 ACIP guidelines recommended the routine use of 13-valent pneumococcal conjugate (PCV13) vaccine for adults aged ≥19 years with certain comorbid conditions, and that PCV13 should be administered to eligible adults in addition to the 23-valent pneumococcal polysaccharide vaccine (PPSV23) that was currently recommended for these groups of adults. The timing of vaccination with PCV13 and PPSV23 is dependent upon if and when an individual has received the other vaccine.

In order to implement the measure consistent with these new guidelines, providers would need reliable, detailed data on: (1) Whether or not a pneumococcal vaccine was previously administered; (2) which type of pneumococcal vaccine (PCV13 vs. PPSV23) was administered; and (3) when it was administered. When considering possible clinical scenarios of screening and vaccinating for pneumonia, current chart and electronic data do not consistently allow for successful abstraction of these varied and detailed historical facts, all of which are needed to appropriately administer a pneumococcal vaccine.

We believe that the measure, as updated by ACIP guidelines, would burden hospitals with data abstraction and yield results with only questionable meaningfulness and reliability. We outlined these pneumococcal vaccination implementation issues in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50780 through 50781), and suspended data collection for IMM–1 until further notice.

Since the suspension of IMM–1, ACIP again updated its 2012 guidelines in

[117] The Centers for Disease Control and Prevention: Key Facts About Seasonal Flu Vaccine. Retrieved from: *http://www.cdc.gov/flu/protect/keyfacts.htm.*

[118] MMWR October 12, 2012. Available at *http://www.cdc.gov/mmwr/PDF/wk/mm6140.pdf.* Accessed on October 31, 2012.

September 2014.[119] In reviewing the updated 2014 guidelines, we held discussions with other HHS agencies to identify implementation strategies for these updated guidelines. However, we were still unable to identify a consistent data source, such as a national immunization registry, that is available to hospitals which would provide sufficient patient-level clinical information to ensure that hospitals would be able to accurately and reliably determine whether they were following the guidelines. There continues to be a lack of detailed and reliable patient level data on prior pneumococcal vaccination that is readily available to all hospitals. Without detailed, reliable, and readily available data for hospitals, it will be difficult to determine if the pneumococcal vaccinations are appropriately administered.

In determining whether to remove the IMM–1 measure, we considered the factors stated above in section VIII.A.3.a. of the preamble of this final rule, in our discussion of considerations for the removal and retention of quality measures from the Hospital IQR Program. Based on the continued lack of ready access to comprehensive patient-level immunization data by hospital staff and the continued infeasibility to implement or align this measure with current clinical guidelines or practice, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24558) we proposed to remove this measure from the Hospital IQR Program. We emphasize that, despite the proposed removal of the IMM–1 measure from the Hospital IQR Program, we understand and value the role pneumococcal vaccines play in preventing pneumococcal disease [120] and we expect hospitals to continue to provide pneumococcal vaccinations for their hospital populations as appropriate.

We invited public comments on this proposal to remove IMM–1 from the Hospital IQR Program beginning in CY 2016 for the FY 2018 payment determination and subsequent years.

Comment: Several commenters supported the removal of the IMM–1 Pneumococcal Immunization measure, while expressing an appreciation for the review and analysis efforts which might have contributed to the decision to remove the measure.

Response: We thank the commenters for their support.

Comment: Several commenters encouraged CMS to reconsider the removal of the pneumococcal immunization measure (IMM–1) and cited the importance of this measure to appropriate patient vaccination. The commenters recommended that CMS refine the measure to better align with the recommendations of the ACIP. One commenter also noted that IMM–1 aligns with CMS and HHS policy goals, and that its removal is in conflict with the stated measure retention criteria. A few commenters noted concern that the proposed removal of IMM–1 is in contrast to the scope of work outlined in CMS' Quality Improvement Network Quality Improvement Organization (QIN–QIO).

Response: We believe that pneumococcal immunization is extremely important in preventing pneumococcal disease. We disagree that removal is in conflict with our removal and retention policy. As discussed above in section VIII.2.a. of the preamble of this final rule, the retention factor ''measure aligns with other CMS and HHS policy goals'' is only one factor we consider in removing or retaining measures. We must also balance other factors and considerations. While a pneumococcal immunization measure aligns with CMS and HHS policy goals, we believe that this measure is infeasible to implement without comprehensive patient-level immunization data, which is not readily available to hospital staff. As indicated, the continued lack of ready access to comprehensive patient-level immunization data by hospital staff and the continued infeasibility to implement or align this measure with current clinical guidelines or practice, are driving factors that support the proposal to remove this measure from the Hospital IQR Program. We emphasize that, despite the proposed removal of the IMM–1 measure from the Hospital IQR Program, we understand and value the role pneumococcal vaccines play in preventing pneumococcal disease. In instances where hospitals have adequate access to a patient's pneumococcal immunization history, we would expect hospitals to provide a pneumococcal vaccination if it were indicated. We also refer hospitals to the ACIP guidelines for additional information on pneumococcal immunization in hospitals *http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html*.

In addition, this measure was not required for the Hospital IQR Program beginning with January 1, 2014 discharges, and was suspended from the program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50780 through 50781). Furthermore, while we recognize that CMS awarded QIOs a four-year contract to improve immunization rates and reduce immunization disparities, we note that QIO performance is not dependent upon vaccination in the hospital setting.[121]

Comment: One commenter expressed concern that CMS has not provided data to support its assertion that hospitals will continue to vaccinate as appropriate.

Response: In instances where hospitals have adequate access to a patient's pneumococcal immunization history, we would expect hospitals to provide a pneumococcal vaccination if it were indicated. The ACIP guidelines (*http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html*) recommended the routine use of 13-valent pneumococcal conjugate (PCV13) vaccine for adults aged ≥19 years with certain comorbid conditions, and that PCV13 should be administered to eligible adults in addition to the 23-valent pneumococcal polysaccharide vaccine (PPSV23) that was currently recommended for these groups of adults.

Comment: One commenter recommends that CMS develop a flow chart that provides hospitals with guidance on whether patients need a pneumococcal vaccination, and which type, based on the patient's vaccination history.

Response: We thank the commenter for its suggestion regarding additional guidance on appropriate vaccination, and will take this recommendation under consideration. We also note that the ACIP guidelines serve as a resource for additional information on pneumococcal immunization in hospitals (*http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html*).

After consideration of the public comments we received, we are finalizing our policy to remove Immunization 1 (IMM–1) Pneumococcal Immunization (NQF #1653) for the FY 2018 payment determination and subsequent years as proposed.

(4) Removal of AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival Measure (NQF #0164)

Our evaluation of the most recently available data shows that AMI–7a is not widely reported by hospitals, and according to the most recent data available, hospitals reporting this

[119] MMWR September 2014. Available at *http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf*.

[120] CDC: Pneumococcal Disease. Retrieved from: *http://www.cdc.gov/pneumococcal/about/prevention.html*.

[121] QIO News: QIN–QIOs Awarded Contracts to Improve Immunization Rates, Reduce Immunization Disparities in 37 U.S. States and Territories. Retrieved from: *http://qioprogram.org/qionews/articles/qin-qios-awarded-contracts-improve-immunization-rates-reduce-immunization*.

measure have less than the required number of cases to be publicly reported. In determining whether to remove AMI–7a as a chart-abstracted measure, we considered the factors stated in above in section VIII.A.3.a. of the preamble of this final rule in our discussion of considerations for the removal and retention of quality measures from the Hospital IQR Program. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24558 through 24559), we proposed to remove AMI–7a as a chart-abstracted measure beginning in CY 2016 for the FY 2018 payment determination and subsequent years because performance on this measure does not result in better patient outcomes. Specifically, measure data are infrequently reported, as most acute myocardial infarction patients receive percutaneous coronary intervention instead of fibrinolytic therapy. In addition, we believe that the burden of requiring all hospitals to report data on this measure, when only a minority of facilities report enough cases to be publicly reported, outweighs the benefits of retaining the chart-abstracted version of this measure.

However, we proposed to retain AMI–7a as an electronic clinical quality measure. We believe that once electronic capture of the measure is possible, the time and resources for electronic reporting should be significantly less as compared to manual abstraction. In addition, as discussed above in section VIII.A.3.a. of the preamble of this final rule, retaining the electronically specified version of a measure allows us to support the alignment of the Hospital IQR Program and the Medicare EHR Incentive Program. In addition, retaining this measure will both allow us to monitor the effectiveness of measure reporting by EHRs and help familiarize hospitals with reporting electronically specified measures under the Hospital IQR Program.

We invited public comments on our proposal to remove the chart-abstracted version of AMI–7a but retain the electronic version for the CY 2016/FY 2018 payment determination and subsequent years.

Comment: Several commenters supported the proposal to remove AMI–7a.

Response: We thank the commenters for their support.

Comment: One commenter requested clarification on whether the chart-abstracted version of AMI–7a is being removed from the Hospital IQR Program, or if the measure is being removed in its entirety, as is the case under the Hospital VBP Program.

Response: We would like to clarify that we are finalizing our proposals to remove the chart-abstracted version of AMI–7a from both the Hospital IQR Program and Hospital VBP Program (see section IV.F.2.b.(2) of the preamble of this final rule). However, we are retaining AMI–7a in its electronic form under the Hospital IQR Program as a measure that may be selected to meet the electronic clinical quality measure requirement for the FY 2018 payment determination.

Comment: Several commenters recommended that both the chart-abstracted and the electronic versions of the AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival measure be removed, and noted that the chart-abstracted version of the measure is being removed because it meets the removal criteria ''Performance or improvement on a measure does not result in better patient outcomes.''

Response: In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24558), we proposed to remove the AMI–7a measure in its chart-abstracted form. We also proposed to retain the measure as an electronic clinical quality measure for the FY 2018 payment determination, despite the reasons cited for removing the chart-abstracted version, in order to support the alignment of the Hospital IQR Program with the Medicare EHR Incentive Program. This would allow us to monitor the effectiveness of measure reporting by EHRs and help familiarize hospitals with reporting electronically. However, we will take this comment into consideration in next year's proposed rule when, as noted above, we may consider removing some electronic clinical quality measures from the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing our policy to remove the chart-abstracted version of AMI–7a Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival Measure (NQF #0164), but retain the electronic version for the CY 2016/FY 2018 payment determination and subsequent years as proposed.

(5) Removal of SCIP-Inf-4 Cardiac Surgery Patients With Controlled Postoperative Blood Glucose (NQF #0300)

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66876), we finalized SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300) for the Hospital IQR Program for FY 2009 and subsequent years. We also stated that hospitals were required to begin submitting data for SCIP-Inf-4 beginning with January 1, 2008 discharges.

Since the finalization of SCIP-Inf-4 for the Hospital IQR Program, the measure underwent routine NQF maintenance endorsement proceedings in 2012. During the NQF maintenance proceedings, the NQF Steering Committee discussed and recommended that the measure assess a lower blood glucose level target and lengthen the timeframe for achieving the lower blood glucose level target. As part of the maintenance endorsement renewal process, SCIP-Inf-4 was modified with the goal of achieving post-operative blood glucose levels of 180 mg/dl at 18–24 hours after surgery (previously, the timeframe was to achieve 200 mg/dl by 6 a.m. on post-operative days 1 and 2). We finalized the adoption of these measure refinements (see revised measure specifications at *http://www.qualityforum.org/QPS/0300*), in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50788) with data collection beginning with January 1, 2014 discharges. We also stated then that we would consider whether additional refinements should be made to better define the 18–24 hour timeframe for the measure.

Since finalizing the refinements to SCIP-Inf-4, we have been contacted by stakeholders and experts in the field of endocrinology regarding the newly refined goal of 180 mg/dl within an 18–24 hour timeframe. Specifically, there are concerns about the following aspects of the measure: (1) Defining ''optimal glycemic control;'' (2) measuring the correlation between optimal glycemic goals and better outcomes; [122] and (3) using an arbitrary 18–24 hour timeframe that does not cover a physiologically meaningful period of time.

Experts in the endocrinology field have shared that providers' enthusiasm to meet the measure blood glucose goals in the specified timeframe may lead to the following unintended consequences: (1) Providers delaying patients' meals until the 24-hour timeframe has passed; (2) providers keeping diabetic patients in intensive care units on insulin drips until the 24-hour timeframe has passed; (3) providers ensuring patients' postprandial glucose levels are kept below 180 mg/dl by concurrent use of intravenous and subcutaneous insulin

[122] Optimal glycemic research for 6 a.m. blood glucose control shows a weak correlation between optimal glycemic goals and better outcomes related to morbidity, mortality and length of stay, suggesting that this type of metric may not be valid. LaPar FJ, Isbell JM, Kern JA, Ailawadi G, Kron IL. Surgical Care Improvement Project measure for postoperative glucose control should not be used as a measure of quality after cardiac surgery. *J Thorac Cardiovasc Surg* 2014;147:1041–8.

administration; and (4) undetected hypoglycemic events caused by using multiple forms of insulin administration since the measure does not assess blood glucose levels past 24 hours. Multiple stakeholders also indicate that the Society of Thoracic Surgeons' guidelines [123] on preoperative through postoperative cardiac surgery glucose control, which helped inform CMS in maintenance of this measure, are currently being reviewed. Newer guidelines will address methods to monitor glycemic control in the post-cardiac surgical patient population. However, these guidelines are not currently available to guide further refinements of SCIP-Inf-4.

In view of stakeholder concerns, the seriousness of the potential negative unintended consequences, and recent analysis that shows the refined measure is ''topped-out,'' on January 9, 2015, we formally suspended the collection of data for SCIP-Inf-4 beginning with July 1, 2014 discharges. We refer readers to *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890406532&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D2015-02-IP.pdf&blobcol=urldata&blobtable=MungoBlobs* for more information about the suspension.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24559), we proposed to remove SCIP-Inf-4 from the Hospital IQR Program effective beginning with CY 2016 discharges for the FY 2018 payment determination and subsequent years. We believe removal of this measure, rather than continued suspension, is appropriate for several reasons. First, performance on this measure does not result in better patient outcomes. Recent literature has highlighted that not meeting optimal glycemic control for a narrow point in time does not result in poorer outcomes.[124] Second, the measure does not align with current clinical guidelines or practice.[125] As previously stated, stakeholders and experts in the field of endocrinology have voiced their concerns in these areas, especially with using an arbitrary 18–24 hour timeframe that does not cover a physiologically meaningful period of time, as current practice guidelines aim for overall glycemic control.[126] Third, public reporting of a measure leads to negative unintended consequences other than patient harm. As mentioned above, these negative unintended consequences include potentially delaying patient meals or transition from the intensive care unit while keeping patients on insulin drips. For more information on the factors we consider for removing or retaining quality measures, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204) and section VIII.A.3.a. of the preamble of this final rule. The measure will remain suspended until CY 2016 discharges begin. Despite our proposed removal of SCIP-Inf-4, we continue to believe glycemic control is important, and we hope to include measures focusing on glycemic control in the Hospital IQR Program in the near future.

We invited public comments on our proposal to remove SCIP-Inf-4 from the Hospital IQR Program for the FY 2018 payment determination and subsequent years.

Comment: Several commenters supported the removal of the SCIP–4 measure, noting that unintended consequences have occurred due to providers' enthusiasm to meet the measure and acknowledging that SCIP-Inf-4 does not align with current practice guidelines. One commenter noted that the measure is being removed in accordance with the measure removal/retention policy described.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that we await the results of the guideline updates put forward by the Society of Thoracic Surgeons before considering the incorporation of metrics of postoperative glucose control in cardiac surgery patients into the Hospital IQR Program. One commenter encouraged CMS to focus on the creation of a better measure that could capture glucose control over time for cardiac surgery patients.

Response: Current practice guidelines, and to our knowledge, future guidelines, will aim for overall glycemic control. SCIP-Inf-4 is specified to evaluate a particular point in time and not overall glycemic control during the postoperative period. If we were to refine the measure to look at overall glycemic control instead of one point in time, this would require many steps, including an environmental scan and literature review to ensure that this is still a gap area that would warrant respecification and testing, as well as MAP input and proposal through rulemaking. These steps would require significant CMS resources, and at this time, we are not considering respecifying this measure. A measure looking at overall postoperative glycemic control would best be developed as an electronic clinical quality measure and tested in this manner. We let our new measure environmental scan and literature review, among other factors, inform our selection of new measures for development. We also target new measures based on many other factors and refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the considerations we use to expand and update quality measure set under the Hospital IQR Program.

Comment: Several commenters supported the proposals to remove the chart-abstracted versions of the nine indicated measures in the Hospital IQR Program and retain them as electronic clinical quality measures. Commenters noted that the removal of these measures reduces administrative burdens on hospitals.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to remove SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300) for the FY 2018 payment determination and subsequent years as proposed.

The table below lists the measures we are finalizing for removal for the FY 2018 payment determination and subsequent years.

[123] Lazar HL, McDonnell M, Chipkin SR, Furnary AP, Engelman RM, Sadhu AR et al. The Society of Thoracic Surgeons Practice Guideline Series: Blood Glucose Management During Adult Cardiac Surgery. A*nn Thorac Surg* 2009; 87: 663–9.

[124] LaPar FJ, Isbell JM, Kern JA, Ailawadi G, Kron IL. Surgical Care Improvement Project measure for postoperative glucose control should not be used as a measure of quality after cardiac surgery. *J Thorac Cardiovasc Surg* 2014;147:1041–8.

[125] Harold L. Lazar HL, McDonnell ME, Chipkin SR, Furnary AP, Engelman RM, Sadhu AR, Bridges CR and Haan CK. The Society of Thoracic Surgeons Practice Guideline Series: Blood Glucose Management During Adult Cardiac Surgery. *Ann Thorac Surg* 2009;87:663–9.

[126] Harold L. Lazar HL, McDonnell ME, Chipkin SR, Furnary AP, Engelman RM, Sadhu AR, Bridges CR and Haan CK. The Society of Thoracic Surgeons Practice Guideline Series: Blood Glucose Management During Adult Cardiac Surgery. *Ann Thorac Surg* 2009;87:663–9.

MEASURES REMOVED FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

''Topped-out'' Measures
• STK–01: Venous Thromboembolism (VTE) Prophylaxis (NQF #0434)
• STK–06: Discharged on Statin Medication * (NQF #0439)
• STK–08: Stroke Education * (NQF endorsement removed)
• VTE–1: Venous Thromboembolism Prophylaxis * (NQF #0371)
• VTE–2: Intensive Care Unit Venous Thromboembolism Prophylaxis * (NQF #0372)
• VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy * (NQF #0373)
Other Measures
• IMM–1 Pneumococcal Immunization (NQF #1653)
• SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300)
• AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival * (NQF #0164)

* Retained as electronic clinical quality measures for the Hospital IQR Program FY 2018 payment determination and subsequent years.

4. Previously Adopted Hospital IQR Program Measures for the FY 2017 Payment Determination and Subsequent Years

a. Background

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50246), we described that the Hospital IQR Program measure set for the FY 2017 payment determination and subsequent years includes a total of 64 measures:

- 6 NHSN measures
- 29 electronic clinical quality measures (voluntary; 12 of these have the option of being reported as chart-abstracted measures)
- 16 chart-abstracted measures (12 of these have the option of being reported as electronic clinical quality measures)
- 21 claims-based measures
- 1 survey measure
- 3 structural measures

In the FY 2015 IPPS/LTCH PPS final rule, we described that of the 63 measures making up the Hospital IQR Program measure set for the FY 2017 payment determination and subsequent years, 42 were previously finalized measures, 11 were measures newly adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49865) and 10 were measures that were determined to be ''topped-out'' but were retained in the Hospital IQR Program as voluntary electronic clinical quality measures (79 FR 50208).

The following table shows measures previously adopted for the Hospital IQR Program FY 2017 payment determination and subsequent years. For a detailed list of the Hospital IQR Program FY 2018 payment determination and subsequent years measure set, we refer readers to section VIII.A.7.f. of the preamble of this final rule.

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
	NHSN	
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
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
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
	Chart-abstracted	
AMI–7a*	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0164
ED–1 *	Median Time from ED Arrival to ED Departure for patients 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 (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
SCIP-Inf-4	Cardiac Surgery Patients with Controlled Postoperative Blood Glucose	0300
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
STK–01	Venous Thromboembolism (VTE) Prophylaxis	0434
STK–04 *	Thrombolytic Therapy	0437
STK–06 *	Discharged on Statin Medication	0439
STK–08 *	Stroke Education	N/A
VTE–1 *	Venous Thromboembolism Prophylaxis	0371
VTE–2 *	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
VTE–5 *	Venous Thromboembolism Discharge Instructions	N/A

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
VTE–6*	Incidence of Potentially Preventable Venous Thromboembolism	N/A
	Claims	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization for Patients 18 and Older.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization for Patients 18 and Older.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
STK Mortality	Stroke 30-day Mortality Rate	N/A
CABG Mortality	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
COPD READMIT	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
STK READMIT	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization	N/A
CABG READMIT	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
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
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 4 (PSI/NSI)	Death among Surgical Inpatients with Serious, Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531
	Electronic Clinical Quality Measures	
AMI–2	Aspirin Prescribed at Discharge for AMI	N/A
AMI–7a*	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0164
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
AMI–10	Statin Prescribed at Discharge	N/A
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	N/A
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
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
HTN	Healthy Term Newborn	0716
PC–01*	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
PC–05	Exclusive Breast Milk Feeding and the Subset Measure PC–05a Exclusive Breast Milk Feeding Considering Mother´s Choice.	0480
PN–6	Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	0147
SCIP–Inf–1a	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0527
SCIP–Inf–2a	Prophylactic Antibiotic Selection for Surgical Patients	0528
SCIP–Inf–9	Urinary Catheter Removed on Postoperative Day 1 (POD 1) or Postoperative Day 2 (POD 2) with Day of Surgery Being Day Zero.	N/A
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–04*	Thrombolytic Therapy	0437
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06*	Discharged on Statin Medication	0439
STK–08*	Stroke Education	N/A
STK–10	Assessed for Rehabilitation	0441
VTE–1*	Venous Thromboembolism Prophylaxis	0371
VTE–2*	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
VTE–3	Venous Thromboembolism Patients with Anticoagulation Overlap Therapy	0373
VTE–4	Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol or Nomogram.	N/A
VTE–5*	Venous Thromboembolism Discharge Instructions	N/A
VTE–6*	Incidence of Potentially Preventable Venous Thromboembolism	N/A
Patient Survey		
HCAHPS	HCAHPS + 3-Item Care Transition Measure (CTM–3)	0166 0228
Structural		
Registry for Nursing Sensitive Care.	Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	N/A
Registry for General Surgery	Participation in a Systematic Clinical Database Registry for General Surgery	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

* Measure is listed twice, as both chart-abstracted and electronic clinical quality measure.

Comment: One commenter requested clarification on whether or not the Sepsis Bundle measure is currently suspended. The commenter had concerns with the sepsis measure as it is currently specified. Specifically, the commenter noted that the measure is abstract, untested, and that elements of the bundle that apply to physical reassessment of patients with persistent hypotension do not have strong evidence supporting a process-outcome link. The commenter recommended the suspension or removal of the measure from the program until the listed concerns are addressed.

Response: We are clarifying here that the Severe Sepsis and Septic Shock: Management Bundle measure (NQF #0500) was suspended in August of 2014,[127] while the measure steward worked with NQF and other stakeholders to incorporate the results of recent studies into NQF #0500's ''element F.'' ''Element F'' included measuring central venous pressure and central venous oxygen saturation; the measure steward was working with NQF and stakeholders on whether this part of ''element F'' should be retained or removed from the measure. On March 26, 2015 [128] we issued a notification announcing that hospitals are required to submit data on the Sepsis Bundle measure for the Hospital IQR Program beginning with October 1, 2015 discharges for the FY 2017 payment determination and subsequent years based on updates to the measure and subsequent NQF re-endorsement.[129]

Since publication of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50236), where we discuss the original finalized version of the measure, changes to the specifications have been undertaken by the steward and endorsed by NQF in response to newly published evidence. Changes have centered on one of the composite elements, referred to as ''Element F.'' These changes do not reflect variations to the measurement strategy. The measure has seven elements. ''Element F'' reassesses the patient for volume status (that is, does the patient have enough fluid in circulation?) and perfusion status (that is, is that fluid circulated appropriately?).

In 2014, the measure was updated so that it reassessed volume and perfusion (Element F) using a complicated and invasive approach to patient care. It called for assessment of central venous pressure (CVP) and percent of oxygen saturation in blood returning to the heart (ScVO2). This assessment required providers to place a long catheter in the patient's neck or chest in a position that approximated the location of the heart. Blood and pressure readings were obtained from this catheter.

The measure has since been updated,[130] again so that the measure reassesses volume and perfusion (Element F) giving providers the opportunity to simply re-examine their patients with a physical exam. Rather than placing an invasive catheter into a patient, requiring consent to do so, and risking complications to patients and hospitals, providers may now simply return to the bedside to manually re-examine their patient. The simple, focused physical exam replaces what was an onerous requirement, and one of the most cited objections to the measure by commenters. Element F now allows a provider choice and does not mandate the use of invasive strategies.

These changes to the requirement to reassess volume and perfusion (Element F) were made after three clinical research studies were published. In March 2014, the Protocolized Care for Early Septic Shock (ProCESS) [131] trial demonstrated that an invasive approach was not required. This trial was followed in October 2014 by the Australian Resuscitation in Sepsis Evaluation Randomized Controlled Trial (ARISE),[132] which arrived at the same conclusion. In March 2015, the Protocolised Management in Sepsis Trial (ProMISe) [133] also reached the same conclusion. NQF and the measure developers acted on the basis of the first trial, ProCESS4, and liberalized the requirement to reassess volume and perfusion (Element F).

The revised Element F only makes compliance with the previously posted

[127] Reference ID 2014–59–IP, Dated August 22, 2014. Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228773795707*.

[128] Reference ID 2015–29–IP; Dated March 26, 2015. Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228774625060*.

[129] *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73701*.

[130] *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73701*.

[131] ProCESS Investigators, Yealy DM, Kellum JA, Juang DT, et al. A randomized trial of protocol-based care for early septic shock. N Engl J Med 2014; 370(18):1683–1693.

[132] The ARISE Investigators and the ANZICS Clinical Trials Group. Goal-directed resuscitation for patients with early septic shock. N Engl J Med 2014; 371:1496–1506.

[133] Mouncey PR, Osborn TM, Power GS, et al for the ProMISe trial investigators. Trial of early, goal-directed resuscitation for septic shock. N Engl J Med 2015: DOI: 10.1056/NEJMoa1500896.

measure easier. The revision retains the same strategy, but makes it easier for hospitals and clinicians to be compliant. The measure is based on the International Guidelines for Management of Severe Sepsis and Septic Shock (2012). Accordingly, the measure has been tested for its reliability and validity and evaluated to determine the importance of collecting measure data.

b. NHSN Measures Standard Population Data

The previously adopted NHSN measures include the CAUTI, CLABSI, MRSA Bacteremia, CDI, colon and abdominal hysterectomy SSI measures, and HCP for the FY 2017 payment determination and subsequent years. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50200 through 50202) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51616 through 51618; 76 FR 51629 through 51633) for more information about these measures. These NHSN measures measure the incidence of HAIs in hospitals participating in the Hospital IQR Program. In order to calculate the NHSN measures for use in the Hospital IQR Program, CDC must go through several steps.

First, CDC determines each NHSN measure's number of predicted infections. CDC determines this number using both specific hospital characteristics (for example, number of central line days for CLABSI) and infection rates that occurred among a standard population (sometimes referred to by CDC as ''national baseline'' but referred to here as ''standard population data''). CDC currently uses data it collected in calendar year (CY) 2009 for the CAUTI measure's standard population data.

In addition, for each NHSN measure, CDC calculates the Standardized Infection Ratio (SIR) by comparing a hospital's reported number of HAIs with the standard population data. For more information about the way NHSN measures are calculated, we refer readers to the QualityNet Web page on HAI measures at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021*.

We are notifying the public that CDC will update the standard population data to ensure the NHSN measures' number of predicted infections reflect the current state of HAIs in the United States. The standard referent population that CDC uses to calculate the Standardized Infection Ratios (SIRs) is comprised of healthcare-associated infection data that CDC's NHSN collects from healthcare facilities throughout the United States for infection events that occurred in a specified baseline time period. Beginning in CY 2016, CDC will use data collected for infection events that occurred in 2015 as the new standard referent population. To do so, CDC will collect HAI data that healthcare facilities are reporting for events that have or will occur in CY 2015 to use in updating the standard population data for HAI measures. This new CY 2015 standard population data for HAI measures will hereinafter be referred to as ''new standard population data.''

While this is not a Hospital IQR Program proposal, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24562), we still invited public input on the CDC's plans to update the standard population data for HAI measures.

Comment: Several commenters supported the plan to use data collected for infection events in 2015 as the new standard referent population, stating that updated population data could help facilitate more accurate comparisons of infection rates.

Response: We thank the commenters for their support.

Comment: A few commenters supported the planned updates to the standard population data for the NHSN measures, but requested that CMS further assess the use of CY 2015 data for CAUTI, noting that due to changes in measure definitions, CY 2015 CAUTI data may not be reflective of actual infection rates.

Response: We appreciate the commenters' views on the stability of the 2015 data. CDC's new CAUTI definition was developed by a subject matter expert working group comprised of CDC and non-CDC participants who systematically assessed each definitional component. The end result is a new CAUTI definition that is simplified from previous iterations and allows for less subjectivity while optimizing clinical credibility. An assessment of the impact of the definition change on CAUTI incidence was completed as part of the definition development. In addition, the NHSN application provides a technical infrastructure and built-in controls on data entry that serve as safeguards against the reporting of events that do not meet the new CAUTI definition. For these reasons, the CDC has informed us of its confidence that the CAUTI data reported in 2015 will be reflective of actual infection rates and appropriate to use for a new standard population.

Comment: A few commenters expressed confusion regarding when CAUTI and CLABSI results would reflect the expanded population reported. In addition, one commenter asked for clarification on when SIR rates will reflect the use of the updated standard population data. That commenter also requested information on when these updates will be reported on *Hospital Compare* for the Hospital IQR Program. In addition, commenters urged CMS to coordinate with CDC to communicate the changes to the public.

Response: As noted above, data collected for infection events occurring in 2015 will be used as the new standard referent population to determine the predicted number of infections beginning for CY 2016/FY 2018 payment determination for CAUTI and CLABSI results as well as SIR rates. For additional clarifications on public display of quality measures, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) or the FY 2012 IPPS/LTCH PPS final rule (76 FR 51608), where we explain that we report data on *Hospital Compare* as soon as is feasible. In addition, we note that CMS continues to coordinate with CDC in regards to communicating with the public.

Comment: One commenter opposed the proposed updates to the standard population of the NHSN measure. Specifically, the commenter expressed concern that the intent of the claims data is to pay bills and not to measure quality. In addition, the commenter noted that the proposed method of HAI data retrieval may not be the most accurate or reliable.

Response: We believe this method of receiving data from the CDC is accurate, reliable and otherwise appropriate, because NHSN users are trained to identify HAIs and report HAI data to NHSN in accordance with standard surveillance protocols, all of which specify the clinical findings and laboratory results that are to be used when reporting to NHSN.[134] In all instances, these protocols avoid use of claims data to make determinations of whether a clinical event should be reported as an HAI to NHSN.

While this was not a Hospital IQR Program proposal, we appreciated public input on the CDC's plans to update the standard population data for HAI measures.

5. Expansion and Updating of Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the

[134] *http://www.cdc.gov/nhsn/acute-care-hospital/index.html.*

considerations we use to expand and update quality measures under the Hospital IQR Program. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24562), we did not propose any changes to these considerations.

6. Refinements to Existing Measures in the Hospital IQR Program

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24562 through 24566) we proposed refinements to the measure cohorts for: (1) The Hospital 30-day, All-cause, Risk-Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization (NQF #0468) measure; and (2) the Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate following Pneumonia Hospitalization (NQF #0506) measure. The proposed refined measures were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP as discussed in its MAP Pre-Rulemaking Report.[135] These measure refinements are discussed in greater detail below.

a. Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) Measure Cohort

(1) Background

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24562 through 24564), we proposed a refinement to the previously adopted Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) measure (hereinafter referred to as the CMS 30-day Pneumonia Mortality Measure), which expands the measure cohort. For the purposes of describing the refinement of this measure, we note that ''cohort'' is defined as the hospitalizations, or ''index admissions,'' that are included in the measure and evaluated to ascertain whether the patient subsequently died within 30 days of the index admission. This cohort is the set of hospitalizations that meet all of the inclusion and exclusion criteria, and we proposed an expansion to this set of hospitalizations.

The previously adopted CMS 30-day Pneumonia Mortality Measure (72 FR 47351) includes hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia. For more cohort details on the measure as currently implemented, we refer readers to the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

The proposed measure refinement would have expanded the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission.

This refinement to the CMS 30-Day Pneumonia Mortality Measure was proposed for several reasons. First, recent evidence has shown an increase in the use of sepsis and respiratory failure as principal diagnosis codes among patients hospitalized with pneumonia.[136] Pneumonia patients with these principal diagnosis codes are not currently included in the measure cohort, and including them would better capture the complete patient population of a hospital with patients receiving clinical management and treatment for pneumonia.

Second, because patients with a principal diagnosis of sepsis and respiratory failure are not included in the current CMS 30-Day Pneumonia Mortality Measure specifications, efforts to evaluate changes over time in pneumonia outcomes could be biased as coding practices change.

Finally, another published study [137] has also demonstrated wide variation in the use of sepsis and respiratory failure codes as principal discharge diagnoses for pneumonia patients across hospitals, potentially biasing efforts to compare hospital performance on 30-day mortality. These published studies and CMS analyses show that hospitals that use sepsis and respiratory failure codes for the principal diagnosis frequently have better performance on the CMS 30-Day Pneumonia Mortality Measure. This coding practice improves performance on the measure because patients with greatest severity of illness (for example, those with sepsis) are systematically excluded from the measure under current measure specifications, leaving only patients with less severity of illness in the cohort.

In response to these emerging data, we examined coding patterns across hospitals caring for Medicare patients and sought to forecast the impact of enhancing or broadening the measure cohort to include the complete patient population, at each hospital, who are receiving clinical management and treatment for pneumonia. Our findings were consistent with a published study.[138] That is, our results suggested that there is: (1) An increasing use of respiratory failure and sepsis as principal discharge diagnoses for pneumonia patients; and (2) wide variation across hospitals in the use of these codes.

In addition to assessing the use of the principal diagnosis codes of sepsis and respiratory failure, we also analyzed coding patterns and the impact of expanding the pneumonia measure to include patients with the principal diagnosis of aspiration pneumonia. We noted after our analyses that aspiration pneumonia: (1) Is a common reason for pneumonia hospitalization, particularly among the elderly; (2) is currently not included in the CMS hospital outcome measure specifications for pneumonia patients; and (3) appears to be similarly subject to variation in diagnosis, documentation, and coding. These findings suggest that a measure with an enhanced or broader cohort for the current CMS 30-Day Pneumonia Mortality Measure will ensure that the measure includes more complete and comparable populations across hospitals. Use of comparable populations would reduce measurement bias resulting from different coding practices across hospitals.

The proposed 30-Day Pneumonia Mortality Measure with this expanded measure cohort was included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014'' with identification number E0468 and has been reviewed by the MAP. The revised measure was conditionally supported

[135] National Quality Forum ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' found at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx* and ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/*.

[136] Lindenauer PK, Lagu T, Shieh MS, Pekow PS, Rothberg MB. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. *Journal of the American Medical Association.* Apr 4 2012;307(13):1405–1413.

[137] Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

[138] Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

pending NQF endorsement of the measure update, as detailed in the ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/*. The refined pneumonia mortality measure will be submitted to NQF for re-endorsement when the appropriate measure endorsement project has a call for measures this year. We will work to minimize potential confusion when publicly reporting the updated measure.

(2) Overview of Measure Cohort Change

The proposed measure refinement expands the cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia that is coded as present on admission. The data sources, exclusion criteria, assessment of the outcome of mortality, and 3 year data evaluation period all remained unchanged.

(3) Risk Adjustment

The statistical modeling approach as well as the measure calculation remained unchanged from the previously adopted measure. The risk adjustment approach also remains unchanged; however, we included additional risk variables to account for the discharge diagnoses added as part of the expanded cohort. For the full measure specifications of the proposed change to the measure, we referred readers to the AMI, HF, PN, COPD, and Stroke Readmission Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(4) Effect of Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization Measure Cohort

Using administrative claims data for FY 2015 (that is, discharges between July 2010–June 2013), we analyzed and simulated the effect of the proposed cohort refinements on the CMS 30-day Pneumonia Mortality Measure as if these changes had been applied for FY 2015. We note that these statistics are for illustrative purposes only, and we did not propose to revise the measure calculations for the FY 2015 payment determination.

Expanding the measure cohort to include a broader population of patients as proposed would have added a large number of patients, as well as additional hospitals (which would now meet the minimum threshold of 25 eligible cases), to the CMS 30-day Pneumonia Mortality Measure. In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881), we established that if a hospital has fewer than 25 eligible cases combined over a measure's reporting period, we would replace the hospital's data with a footnote indicating that the number of cases is too small to reliably determine how well the hospital is performing. These cases are still used to calculate the measure; however, for hospitals with fewer than 25 eligible cases, the hospital's mortality rates and interval estimates are not publicly reported for the measure. For more information about this minimum case threshold for public reporting, we refer readers to section VIII.A.13. of the preamble of this final rule. The increase in the size of the measure cohort proposed in the FY 2016 IPPS/LTCH PPS proposed rule would have changed results for many hospitals and would change the number of hospitals that have greater than 25 cases.

The previously adopted pneumonia mortality measure cohort includes 976,590 patients and 4,418 hospitals for the FY 2015 payment determination. We noted the following effects for the CMS 30-Day Pneumonia Mortality Measure if the proposed expanded cohort had been applied for FY 2015: (1) The expansion of the cohort would include an additional 686,605 patients (creating a total measure cohort size of 1,663,195 patients); (2) an additional 86 hospitals would meet the minimum 25 patient cases volume threshold over the 3-year measure period and would be publicly reported for the measure; (3) 41 percent of the refined measure cohort would consist of patients with a principal discharge diagnosis of aspiration pneumonia and patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission; and (4) there would be an increase in the number of hospitals considered outliers and a shift in some hospitals' outlier status classification, for example from ''better than the national rate'' to ''no different than the national rate'' or from ''worse than the national rate'' to ''no different than the national rate.''

A detailed description of the refinements to the CMS 30-Day Pneumonia Mortality Measure and the effects of the change are available in the AMI, HF, PN, COPD, and Stroke Readmission Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We note that this file contains information for both Mortality and Readmission.

We invited public comment on our proposal to refine the previously adopted Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) measure, expanding the measure cohort.

Because comments for this proposal also overlap with those for the next section (VIII.A.6.b. of the preamble of this final rule (Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506) Measure Cohort)), we address comments related to both proposals after the next section.

b. Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) Measure Cohort

(1) Background

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24564 through 24566), we proposed a refinement of the previously adopted measure, Hospital 30-day all-cause, risk-standardized readmission rate following pneumonia hospitalization (NQF #0506) (hereinafter referred to as the CMS 30-Day Pneumonia Readmission Measure) which expands the measure cohort. For the purposes of describing the refinement of this measure, we note that ''cohort'' is defined as the hospitalizations, or ''index admissions,'' that are included in the measure and evaluated to ascertain whether the patient was subsequently readmitted to the hospital within 30 days of the index admission. This cohort is the set of hospitalizations that meets all of the inclusion and exclusion criteria and we proposed an expansion to this set of hospitalizations.

The previously adopted CMS 30-Day Pneumonia Readmission Measure, as specified in the FY 2009 IPPS PPS proposed rule (73 FR 23648) and adopted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780 through 68781), includes hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia. For measure cohort details of the currently implemented measure, we refer readers to the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Readmissions Update zip file on our Web site at: *http://www.cms.gov/*

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology.html.

This proposed measure refinement would have expanded the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. The determination to refine the measure cohort was based on our evaluation of both the frequency and variation in utilization of these diagnosis codes, as such coding practices have been described in recently published studies.

This refinement to the CMS 30-Day Pneumonia Readmission Measure was being proposed in response to recent evidence showing increasing use of the principal diagnosis codes of sepsis and respiratory failure among patients hospitalized with pneumonia. Including such patients could better represent the complete population of a hospital's patients who are receiving clinical management and treatment for pneumonia. In addition, because patients with a principal diagnosis of sepsis and respiratory failure are not included in the current CMS 30-Day Pneumonia Readmission Measure specifications, efforts to evaluate changes over time in pneumonia outcomes could be biased as coding practices change.

Wide variation exists in the use of sepsis and respiratory failure codes across hospitals, potentially biasing efforts to compare hospital performance on 30-day readmission rates.[139] While the referenced study [140] evaluated the effect of coding practices on mortality measure performance, the rationale is applicable to readmission measure performance as well. The increased use of sepsis and respiratory failure diagnosis codes improves performance because the patients with greatest severity of illness (for example, those with sepsis or respiratory failure) are currently systematically excluded from the measure, leaving only patients with lesser severity of illness in the measure cohort.

In response to this emerging data, we examined coding patterns across hospitals caring for Medicare patients and sought to forecast the impact of broadening the measure cohort to include the complete population of patients at each hospital who are receiving clinical management and treatment for pneumonia. Our findings were consistent with a published study [141] for mortality; that is, our results suggested that there is an increasing use of respiratory failure and sepsis as principal discharge diagnoses for pneumonia patients, as well as showed wide variation across hospitals in the use of these codes. In addition to assessing the use of the principal diagnosis codes of sepsis and respiratory failure, we also analyzed coding patterns and the impact of expanding the pneumonia measure to include patients with the principal diagnosis of aspiration pneumonia. We noted after our analyses that aspiration pneumonia: (1) Is a common reason for pneumonia hospitalization, particularly among the elderly; (2) is currently not included in the CMS hospital outcome measure specifications for pneumonia patients; and (3) appears to be similarly subject to variation in diagnosis, documentation, and coding. These findings suggest that expanding the measure cohort for the current CMS 30-Day Pneumonia Readmission Measure will ensure the measure includes more complete and comparable populations across hospitals. Use of comparable populations would reduce measurement bias resulting from different coding practices seen across hospitals. We believe that measure results derived from refinement of the measure cohort in the manner we proposed, which will include additional pneumonia patients that are not being included under the current measure specifications, will improve the fidelity of the measure's assessment of quality and outcome for pneumonia.

The proposed refined measure was included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014'' with identification number E0506, has been reviewed by the MAP, and was conditionally supported pending NQF review of the measure update. In particular, MAP members noted that the measure should be considered for sociodemographic status (SDS) adjustment in the upcoming NQF trial period, reviewed for the empirical and conceptual relationship between SDS factors and risk-standardized readmission rates, and endorsed with appropriate consideration of SDS factors as determined by NQF standing committees. We refer readers to the ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/* for more information. When the appropriate measure endorsement project has a call for measures in 2015, this measure will be submitted to the NQF for reendorsement with special consideration of the potential impact of SDS adjustment on the measure.

(2) Overview of Measure Cohort Change

The proposed measure refinement would have expanded the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia that is coded as present on admission. The data sources, exclusion criteria, assessment of the outcome of readmission, and previous 3 years data evaluation period remained unchanged.

(3) Risk Adjustment

The statistical modeling approach as well as the measure calculation remained unchanged from the previously adopted measure. The risk adjustment approach also remains unchanged; however, we included additional risk variables to account for the discharge diagnoses added as part of the expanded cohort. For the full measure specifications of the proposed changes to the measure, we referred readers to the AMI, HF, PN, COPD, and Stroke Readmissions Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology.html*.

(4) Effect of Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization Measure Cohort

Using administrative claims data for FY 2015 (that is, discharges between July 2010–June 2013); we analyzed and simulated the effect of the proposed measure cohort refinements on the CMS 30-Day Pneumonia Readmission Measure as if these changes had been applied for FY 2015. We note that these statistics are for illustrative purposes

[139] Rothberg MB, Pekow PS, Priya A, Lindenauer PK.: Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

[140] Rothberg MB, Pekow PS, Priya A, Lindenauer PK.: Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

[141] Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

only, and we did not propose to revise the measure calculations for the FY 2015 payment determination. We anticipate that this measure will first be publicly reported with the proposed cohort change in CY 2016.

Based on our analysis, we anticipate that expanding the measure cohort to include a broader population of patients as proposed would have added a large number of patients, as well as additional hospitals (which would now meet the minimum threshold of 25 eligible cases), to the CMS 30-Day Pneumonia Readmission Measure. In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881), CMS established that if a hospital has fewer than 25 eligible cases combined over a measure's reporting period, we would replace the hospital's data with a footnote indicating that the number of cases is too small to reliably tell how well the hospital is performing. These cases are still used to calculate the measure; however, for hospitals with fewer than 25 eligible cases, the hospital's readmission rates and interval estimates are not publicly reported for the measure. For more information about this minimum case threshold for public reporting, we refer readers to section VIII.A.13of the preamble of this final rule. The increase in the size of the measure cohort proposed in FY 2016 IPPS/LTCH PPS proposed rule for this measure cohort would have changed results for many hospitals and would change the number of hospitals that have greater than 25 cases.

The previously adopted pneumonia readmission measure cohort includes 1,094,959 patients and 4,451 hospitals for FY 2015 payment determination. We noted the following effects for the CMS 30-Day Pneumonia Readmission Measure if the proposed expanded cohort had been applied for FY 2015: (1) The expansion of the CMS 30-Day Pneumonia Readmission Measure cohort would include an additional 670,491 patients (creating a total measure cohort of 1,765,450 patients); (2) there would be an additional 67 hospitals that meet the minimum 25 patient cases volume threshold over the 3-year applicable period and would be publicly reported for the measure; (3) patients with a principal discharge diagnosis of aspiration pneumonia and patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission would represent 38 percent of the total expanded measure cohort; and (4) there would be an increase in the number of hospitals considered outliers and a shift in some hospitals' outlier status classification, for example from ''better than the national rate'' to ''no different than the national rate'' or from ''worse than the national rate'' to ''no different than the national rate.''

A detailed description of the refinements to the CMS 30-Day Pneumonia Readmission Measure and the effects of the change are available in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We invited public comment on our proposals to refine the previously adopted Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506) measure, and the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization (NQF #0468) measure which expands the measure cohort.

Comment: Several commenters supported CMS' proposal to expand the cohort for identifying Pneumonia patients for the two PN measures, and noted that the expanded cohort would address the concern of coding variation. One commenter encouraged CMS to expand this cohort to also apply to the Payment Episode for PN. Another commenter noted the refinement would better reflect the population of patients who are managing and being treated for pneumonia. One commenter supported the proposed refinement to the Hospital 30-day, All-Cause, Risk-Standardization Readmission Rate following Pneumonia Hospitalization (NQF #0506) measure, indicating that the expanded cohort would address the concern of coding variation. Another commenter supported the proposed cohort expansions for the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization and Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization measures.

Response: We thank the commenters for their support and are considering updating other measures that contain the same pneumonia cohort, such as the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia measure, which uses the same cohort as the currently reported Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure.

Comment: One commenter commended CMS' proposal and associated rationale for incorporating the refinements to the patient populations for the pneumonia mortality and readmission measures. The commenter agreed with CMS that, without modification, the current specifications may result in significant variation in the number of pneumonia cases captured due to differences in hospital coding and that, by refining the population for these measures, CMS will ensure better collection of more complete and comparable data across hospitals.

Response: We thank the commenter for its support.

Comment: Many commenters expressed concern that the proposed Refinements of the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization and the Hospital 30-Day, All-Cause, Risk-Standardized Readmissions Rate Following Pneumonia Hospitalization measure cohorts, stating that the proposed expansions of the measures were not revisions, but a wholesale expansion which could have unintended consequences. The commenters also noted concern that these changes could inappropriately expand the measure to a population of patients with greater severity of illness and higher costs. One commenter acknowledged that although some risk-adjustment processes were proposed, the adequacy of the revised risk adjustment for handling the expanded population is unknown. Finally, some commenters noted concern that the measures do not appropriately account for variation in patient acuity and that hospitals treating the sickest patients will appear to perform poorly. One commenter also suggested that the expansion could artificially increase readmission rates unless the measures are risk-adjusted.

Response: We appreciate the commenters' concerns about the extent of the expansion of these measures and the inclusion of patients with greater illness severity.

In the proposed rule, we described an expanded measure cohort that included patients with: (1) A principal discharge diagnosis of bacterial/viral pneumonia; (2) a principal discharge diagnosis of aspiration pneumonia; (3) a principal discharge diagnosis of sepsis if pneumonia was POA; (4) a principal discharge diagnosis of severe sepsis (including septic shock) if pneumonia was POA; and (5) principal discharge diagnosis of respiratory failure if pneumonia was POA. We also proposed including the presence of sepsis or respiratory failure in the index admission as covariates, or risk-adjusters, in the model.

However, analyses conducted after publication of the proposed rule as part of the measure reevaluation and respecification process revealed challenges to risk adjustment with respect to patients with severe sepsis and respiratory failure, and suggested that this proposed cohort expansion could exacerbate the bias in the existing measure that it was intended to mitigate. Specifically, hospital coding frequency was found to be even more strongly, and inversely, associated with performance; hospitals with the greatest proportion of patients receiving a principal diagnosis of sepsis or respiratory failure had the lowest risk-adjusted mortality and were more likely to be 'better-performing' outliers. This finding was concerning, because clinically, we do not expect differences in coding practices to be related to performance on the measure. Our aim was to expand the cohort to adequately capture the wide range of pneumonia patients across hospitals, regardless of coding patterns, but that would adequately account for different degrees of illness among the hospitals' population.

The reevaluation and respecification of the proposed expansions resulted in measure cohorts that are a broader clinical representation than the currently reported measures cohorts and that account for the wider spectrum of clinical severity of pneumonia among Medicare beneficiaries receiving acute care at IPPS U.S. hospitals. During this subsequent analysis, the measures were then modified so that the cohorts were expanded to only include: (1) Patients with a principal discharge diagnosis of pneumonia (current reported cohort), (2) patients with a principal discharge diagnosis of aspiration pneumonia, and (3) patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia that was POA. Patients with: (4) A principal discharge diagnosis of severe sepsis (including septic shock) if pneumonia was POA; and (5) principal discharge diagnosis of respiratory failure if pneumonia was POA were not included. The finalized measures, with the modified expanded cohort, also do not include additional risk variables for the presence of sepsis or respiratory failure in index admission as part of the measures' risk-adjustment since the patients with respiratory failure or severe sepsis will not be included in the finalized measures. This respecification was determined to be statistically robust, such that in the finalized measures, with the modified expanded cohort, risk-standardization adequately accounted for case-mix differences across hospitals, without being confounded by hospital coding patterns. Furthermore, this respecification is also consistent with clinical patterns of care, as the very sickest patients (those with principal discharge diagnosis of severe sepsis or respiratory failure) often require care in an intensive care unit (ICU) and other specialized interventions (such as ventilator support) that is clinically distinct from the care provided to patients with less severe forms of pneumonia.

These analyses led to our decision to not include the sickest patients in the refinements of the Hospital 30-day, All-Cause, Risk Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization (NQF #0468) measure and the Hospital 30-day, All-Cause, Risk Standardized Readmission Rate following Pneumonia Hospitalization (NQF #0506) measure. Upon this further analysis and in response to public comment, we are modifying our proposal and finalizing a modified version of the expanded pneumonia cohort. Instead of including all five proposed diagnosis categories as described above, we are finalizing only three: (1) Patients with a principal discharge diagnosis of pneumonia (the current reported cohort); (2) patients with a principal discharge diagnosis of aspiration pneumonia; and (3) patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia POA. We are not including patients with the most severe illness, which are represented in the two patient groups we are not finalizing: (4) Patients with a principal discharge diagnosis of respiratory failure; and (5) patients with a principal discharge diagnosis of severe sepsis (including septic shock). As a result, we are also not finalizing our proposal to risk adjust with respect to these two conditions being present during the index admission.

We find that this modified cohort expansion produces a measure that does not favor or disadvantage hospitals on the basis of their coding practices. Although the modified expansion of the cohort for these measures will increase the number of included patients and change the national readmission and mortality rates, we do not believe this constitutes a new measure; the intent of the measure has not changed since initial development and NQF endorsement. The modified measures will not expand the population by as much or change the national rate as much as noted in the proposed rule. The modified mortality measure cohort will be approximately 18 percent smaller than what was proposed and the modified readmission measure cohort will be approximately 15 percent smaller than what was proposed.

We believe the modified versions of the measure refinements being finalized effectively broadens the cohort of patients included to be more clinically comprehensive than that of the current reported measures (bringing in sepsis and aspiration pneumonia patients), but avoids including patients that are most severely ill on arrival (those with severe sepsis and respiratory failure). Those patients' increased risk was challenging to appropriately account for across hospitals. By limiting measure expansion without including risk-adjustment for these alternate principal diagnoses (that is, severe sepsis and respiratory failure), we brought in a large portion of patients currently excluded from the measures, but mitigated the biases introduced by hospital coding patterns.

Based on our additional evaluation, we confirmed that after removing the risk variables for sepsis and respiratory failure during the index admission from the previously proposed approach, risk-adjustment was effective for the modified refinements to the measures, as hospital coding frequency was no longer associated with performance on either the mortality or readmission measures. As was previously proposed, the risk adjustment factors used in the current publicly reported versions of the mortality and readmission measures [142] [143] were retained, with the addition of 5 new risk-adjustment variables (Septicemia/sepsis (CC2), Disorders of fluid/electrolyte/acid-base (CC23), Delirium and encephalopathy (CC48), Respiratory dependence/tracheostomy (CC77), Decubitus ulcer of skin (CC148)) and two modified risk-adjustment variables (addition of Pleural effusion/pneumothorax (CC114) and respiratory arrest (CC78) to existing risk-adjustment variables) for the mortality measure and 1 new risk-adjustment variable (respiratory dependence/tracheostomy (CC77)) for the readmission measure. No additional risk adjustment variables were added for the patients included in the modified expanded cohort (that is, aspiration pneumonia and sepsis patients). The

[142] For more cohort details on the measure as currently implemented, we refer readers to the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[143] Pneumonia RSMR finalized at (72 FR 473510) and Pneumonia RSRR finalized at (76 FR 51666 through 51667).

previously proposed risk adjustment approach (now excluding variables for sepsis, and respiratory failure present during the index admission) adequately accounts for the varying severity and comorbidities of patients across the finalized, modified cohort; therefore, hospitals will not be unfairly penalized for treating sicker patients. Specifically, hospital performance among those with higher rates of patients with sepsis or aspiration pneumonia is similar to those with fewer such patients, suggesting that the risk-adjustment methodology adequately accounts for the differences in risk among the subgroups of patients. For details of the modified refinements of the measures we are finalizing, including risk-adjustment and impact on hospitals, we refer readers to the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: Many commenters opposed the expansion of the patient cohorts for the Refinement of PN Mortality Cohort: 30-Day, All-Cause, Risk-Standardized Mortality Rate and the Refinement of PN Readmission Cohort: 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) measures until the proposed changes have been reviewed by the National Quality Forum. One commenter stated that the preliminary information provided in the proposed rule and to the MAP in December was not sufficient for evaluation, and that additional information regarding the measures' reliability, validity and appropriateness must be fully considered. Specifically, the commenter was not convinced that CMS has provided enough evidence to support such a significant expansion of these measures at this time, with the commenter's own analysis indicating that cohort size could increase 67 percent. Several commenters also expressed concern that the conditions proposed by the MAP were not addressed with regard to NQF endorsement.

Response: As noted in both measure refinement discussions above, the MAP conditionally supported these refined measures during the 2014 MAP Hospital Workgroup Meeting and conditionally supported them pending NQF review of the updates. We do not agree that the information presented to the MAP was insufficient, because while the MAP provides a recommendation on whether measures are appropriate for a program, it does not provide an in-depth review of evidence and testing. The NQF review, on the other hand, provides stakeholders an opportunity for in-depth review of such aspects.

In addition, we believe the finalized measures' (with the modified expanded cohort) reliability, validity and appropriateness are sufficient. CMS' reliability testing demonstrated moderate reliability that is comparable to other CMS claims-based outcome measures. The finalized measures, with the modified expanded cohort, have both clinical and face validity. The inclusion of additional patient groups is based on research findings and an aim to maintain clinically comparable cohorts across hospitals. The validity of the measures is further based on prior findings demonstrating the adequacy of claims-based risk-adjustment outcome measures. Furthermore, the finalized measures' validity is based on the demonstration that they mitigate biases introduced by hospital coding patterns. For more details on the measures, including predictive ability, reliability, and validity, we refer readers to the measure methodology reports in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. This data was presented to the MAP and will also be included in the NQF applications.

When the appropriate measure endorsement project has a call for measures in 2015, the finalized measures, with the modified expanded cohorts, will be submitted to the NQF for reendorsement. The original 30-day, All-Cause, Risk-Standardized Readmission Rate following Pneumonia Hospitalization and 30-day, All-Cause, Risk-Standardized Mortality Rate following Pneumonia Hospitalization measures were previously NQF-endorsed, and we do not believe the intent of the measures have changed.

Comment: Some commenters did not support the inclusion of aspiration pneumonia in the cohort for the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) and the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) measures. One commenter noted that these diagnoses have different causes and associated risks and that patients with these diagnoses may have higher acuity, higher mortality and readmission rates, and more comorbidities than patients with community acquired pneumonia. Another commenter noted concern that the majority of patients with aspiration pneumonia are medically frail patients with comorbidities that predispose them to recurrent aspiration events and another was concerned that stroke patients can be at higher risk for re-aspiration and therefore pneumonia readmission. This commenter further suggested that the measure could inappropriately become a catch all for neuro-muscular diseases, CVA, head injury, advanced dementia, among other diagnoses, which would not measure true pneumonia readmissions.

Response: The purpose of expanding the cohort of the current pneumonia readmission measure is to include a broader spectrum of pneumonia patients and respond to changes in coding practices that were potentially biasing estimates of the performance of hospitals. We believe the modified expanded cohorts for the finalized measures effectively broaden the patients included in the measure to be more clinically comprehensive (bringing in sepsis and aspiration pneumonia patients) but avoids including those patients that are most severely ill on arrival (those with severe sepsis and respiratory failure).

We appreciate the commenters concerns that community acquired pneumonia and aspiration pneumonia have different causes and associated risks (for example, recurrent aspiration due to other comorbidities). While the pathological causes of aspiration pneumonia are slightly different from the causes of community acquired pneumonia, in routine clinical practice, evidence shows it can be very challenging for physicians to differentiate aspiration syndromes including pneumonitis and pneumonia, from other types of pneumonia included in the measure. This is reflected in the tremendous variation across hospitals in the use of aspiration pneumonia diagnosis codes. This variation suggests that hospitals are not consistently distinguishing between these conditions as distinct subtypes regardless of patients' comorbid conditions.

Moreover, the treatment of patients hospitalized for pneumonia, aspiration pneumonia, or sepsis due to pneumonia is very similar and involves treatment with antibiotics, IV fluids, and symptom management. In addition, although some patients with aspiration pneumonia, such as medically frail patients or those who have suffered a stroke as noted by the commenter, have a higher predicted mortality or readmission risk, many of the associated

comorbidities, are captured in the measures' risk-adjustment methodology. For example, the risk models include clinical history of stroke, as well as conditions associated with frailty, such as neuromuscular disease, and dementia. Therefore, we do not believe that the measure would inappropriately become a catch-all for neuro-muscular diseases, cerebrovascular accident (CVA), head injury, advanced dementia, among other diagnoses, which would not measure true pneumonia readmissions. Our analyses, as described above and in the measure methodology reports (available in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*), show that hospital performance among hospitals with higher rates of patients with aspiration pneumonia is similar to those with fewer such patients, confirming that the risk-adjustment methodology adequately accounts for the differences in risk among the subgroups of patients.

Comment: One commenter suggested that CMS should consider stratifying the measures, and evaluate the impact of the proposed change on hospital performance, as it is currently unknown.

Response: We appreciate the suggestion to consider stratification of the measure. Stratification can be used as a means to account for differences among subgroups of patients within a measure. It can be used to report outcomes separately for different groups, unadjusted by a risk model. For example, a measure may specify stratification of results within a major clinical category (for example, diabetes) by severity or other clinical differences, as well as by race or age category. However, we did not find that stratification was required in the modified expanded cohort that is being finalized for these measures because risk adjustment adequately accounts for the varying severity and comorbidities of patients across the finalized cohort. Therefore, hospitals will not be unfairly penalized for treating sicker patients.

Specifically, our analyses found that hospital performance among hospitals with higher rates of patients with sepsis or aspiration pneumonia hospital performance is similar to those with fewer such patients, suggesting that the risk adjustment methodology adequately accounts for the differences in risk among the subgroups of patients; further information can be found in the subsequent link provided. Details regarding the number of hospitals that would change performance categories and how their performance is related to their coding practices is detailed in the measure specifications report for the measure as finalized are provided in the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: Some commenters advised CMS to articulate its public reporting approach for both the old and new versions of the measures so that the observed changes are not perceived as changes in care by consumers. In addition, one commenter noted that previous pneumonia mortality and readmission data and benchmarks did not include patients with this expanded set of diagnoses, so the change may erroneously show worsening hospital performance on these measures. One commenter recommended that CMS develop a communication strategy regarding the changes to the measures and the impact of those changes on public reporting.

Response: We note that consumers typically view the main *Hospital Compare* Web site: *http://www.medicare.gov/hospitalcompare/search.html*, which does not include information about how hospitals performed in the past, only how they are currently performing as compared to the national rate. Archived hospital performance data is instead available at: *https://data.medicare.gov/data/archives/hospital-compare*. While hospitals may shift performance categories (for example, from worse than to better than the national rate) between the current publically reported and finalized measures (with modified expanded cohorts), we do not believe measure rates over time will be abundantly evident to consumers. Nonetheless, we will ensure that adequate information be available to the public regarding which version of the measures are displayed on *Hospital Compare* to reduce any potential confusion for consumers.

Comment: Some commenters recommended that CMS conduct a study to validate the expanded measures and one recommended a review by outside experts.

Response: We will submit the finalized measures with the modified expanded cohort to the NQF for review when the appropriate project is called. The NQF will assess the modified, refined measures for validity. As discussed above, we determined the finalized readmission and mortality measures with the modified expanded cohorts to have both clinical and face validity. Prior studies have demonstrated that using comorbidity information from administrative claims is a valid approach to risk adjustment and adequately assesses the difference in case mix among hospitals. Furthermore, the finalized measures have greater validity than the current publically reported measures, because they mitigate biases introduced by hospital coding patterns. A detailed description of the refinements to the CMS 30-Day Pneumonia Readmission and Mortality Measures and the effects of the changes are available in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: One commenter noted that hospitals have not had the opportunity to develop and evaluate interventions for the proposed expanded cohort. The commenter suggested that hospitals be given an entire performance period of cohort expansion knowledge, and requested that CMS delay the proposed expansion until FY 2021.

Response: These measure refinements focus on coordination-of-care and care-transitions interventions to reduce mortality and readmissions. These practices, such as ensuring appropriate follow-up post-discharge and medication reconciliation, should already be in place for patients in hospitals and would not differ greatly for the modified expanded cohort of patients included in the measure refinements being finalized. Therefore, we do not agree with delaying the implementation of these measures, especially because the publicly reported versions of the measures are subject to bias resulting from differences in coding patterns among hospitals, which the refined measures address. We believe that this refinement provides a less biased and more comprehensive look at pneumonia patients.

Comment: One commenter agreed with the addition of respiratory failure and sepsis with a secondary diagnosis of pneumonia, as their inclusion will provide a better account of pneumonia readmissions.

Response: As discussed above, after extensive evaluation and analysis of the results of the proposed refinement of these measures, we are finalizing, with modifications, the refinements to both measures without the inclusion of

patients with a principal diagnosis of respiratory failure or severe sepsis in the expanded cohort. We refer readers to our responses above.

Comment: One commenter expressed concern that one of the cited studies noted their risk adjustment approach was insufficient and could penalize hospitals treating sicker patients, and that the CMS approach was similar.

Response: We refer readers to our earlier responses to comments for a more detailed discussion on the rationale for finalizing the modified expanded cohort and not the proposed expanded cohort. We believe the modified version of the measure refinements being finalized effectively broadens the cohort of patients included in the measures to be more clinically comprehensive (bringing in sepsis and aspiration pneumonia patients), but avoids including those patients in the proposed expanded cohort that are most severely ill on arrival (those with severe sepsis and respiratory failure). After removal of the most severely ill, the modified risk adjustment model being finalized adequately accounts for the varying severity and comorbidities of patients across the modified cohort; therefore, we believe that hospitals will not be unfairly penalized for treating sicker patients. As described in more detail above, our analyses demonstrated that hospital performance among hospitals with higher rates of patients with sepsis or aspiration pneumonia is similar to those with fewer such patients, suggesting that the risk adjustment methodology adequately accounts for the differences in risk among the subgroups of patients.

After consideration of the public comments we received and extensive evaluation and analysis of the results of the refined measures, we are finalizing a modified version of the measure refinements (expanded pneumonia cohort) proposed for the FY 2017 payment determination and subsequent years for both the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506) measure and the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization (NQF #0468) measure. Instead of including all five proposed diagnosis categories, we are finalizing only three: (1) Patients with a principal discharge diagnosis of pneumonia (the current reported cohort); (2) patients with a principal discharge diagnosis of aspiration pneumonia; and (3) patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia coded as present on admission (POA). We are not including patients with the most severe illness, which are represented in the 2 diagnosis categories we are not finalizing: (1) Patients with a principal discharge diagnosis of respiratory failure with a secondary diagnosis of pneumonia present on admission; and (2) patients with a principal discharge diagnosis of sepsis (including septic shock) with a secondary diagnosis of pneumonia present on admission. As a result, we are also not finalizing our proposal to risk adjust with respect to these two conditions.

7. Additional Hospital IQR Program Measures for the FY 2018 and FY 2019 Payment Determinations and Subsequent Years

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24566 through 24581), we proposed to add eight new measures to the Hospital IQR Program for the FY 2018 payment determination and subsequent years. We proposed to adopt seven new claims-based measures and one new structural measure: (1) Hospital Survey on Patient Safety Culture (structural); (2) Kidney/UTI Clinical Episode-Based Payment measure (claims-based); (3) Cellulitis Clinical Episode-Based Payment measure (claims-based); (4) Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure (claims-based); (5) Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment measure (claims-based); (6) Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based); (7) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (claims-based); and (8) Excess Days in Acute Care after Hospitalization for Heart Failure (claims-based).

The proposed measures were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014'' [144] in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2015 Final Recommendations.[145]

For purposes of the Hospital IQR Program, section 1886(b)(3)(B)(IX)(aa) 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 currently holds this contract. However, section 1886(b)(3)(B)(IX)(bb) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We invited public comment on each of the proposed measures listed above. We address general comments received on all proposed measures here and discuss more specific comments in subsequent sections below.

Comment: One commenter expressed concern regarding the continued use of claims data for some measure reporting, noting that there is variation in coding practices across hospitals, and that unlike chart-abstracted data, internal validation practices may not occur. The commenter recommended that CMS regularly perform audits of hospital coding practices and require hospitals to annually attest that they are following specific coding practices.

Response: We thank the commenter for their suggestion and note that we rely on accurate claims data for both billing and quality reporting purposes. We believe that claims-based measures are valuable forms of data that do not add to hospital burden. In addition, we disagree with the commenter's suggestion that we should require hospitals to attest that they are following specific coding practices, as we believe this would pose an unnecessary burden on hospitals. We continue to rely on the Medicare Claims Review Programs,[146] (a collection of initiatives enacted to prevent or identify and recover improper payments before CMS processes a claim, and to identify and recover improper payments after processing a claim) to conduct audits of hospital coding practices, if appropriate.

Comment: Many commenters opposed the proposal to include eight new measures in the Hospital IQR Program;

[144] Measure Applications Partnership: List of Measures Under Consideration (MUC) for December 1, 2014. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318.*

[145] National Quality Forum ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx* and ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/.*

[146] *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MCRP_Booklet.pdf.*

indicating that the lack of NQF endorsement poses questions about their reliability, validity, and feasibility. The commenters also noted that the measures do not address any national priority area or goal for improving care, or concerns over institutional behavior.

Response: We acknowledge the credibility of NQF endorsement, however, section 1886(b)(3)(B)(IX)(bb) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We also reviewed the NQF-endorsed measures and were unable to identify any other NQF-endorsed measures that addressed excess days in acute care or the clinical episode-based payment conditions. Regardless, as discussed previously and below, all measures being finalized in this rule will be submitted for NQF endorsement when the next call for measures opens except the Hospital Survey on Patient Safety Culture measure. This measure may be a time-limited measure that will assist us in assessing the feasibility of implementing a single survey on patient safety culture in the future.

In addition, all of the proposed measures were reviewed by the MAP, as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2015 Final Recommendations, indicating that they have been determined to be appropriate for the Hospital IQR Program. We note that measure developers conduct reliability and validity testing and that the MAP considers whether the measure under consideration is appropriate for a program.[147] Aside from the structural measure (Hospital Survey on Patient Safety Culture), the development and testing (including validity and reliability) results of the finalized measures has undergone review by physicians from a variety of specialties and more details concerning testing results of these measures are detailed in the methodology reports that are mentioned under each measure section. Furthermore, feasibility is not an issue of concern since the claims-based measures are calculated by CMS using administrative claims data.

Finally, we note that we specifically select and propose measures that address goals for improving care and that the measures being finalized in this final rule all address NQS or CMS Quality Strategy Goals, which include[148] making care safer by reducing harm strengthening person & family engagement as partners in care, promoting effective communication & coordination of care, promoting effective prevention & treatment of chronic diseases, community coordination to promote ''best practices'' of healthy living, and making care affordable.

The factors we take into account in implementing and expanding the Hospital IQR Program are described in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510).

Comment: A few commenters recommended that CMS consider adopting the recommendations outlined in the Institute of Medicine's (IOM) Vital Signs report for streamlining and focusing national quality measurement efforts.

Response: We refer readers to *http://iom.nationalacademies.org/~/media/Files/Report%20Files/2015/Vital_Signs/VitalSigns_RB.pdf* for recommendations outlined in the Institute of Medicine's (IOM) Vital Signs report. We thank the commenters for this suggestion and will take this under consideration.

Comment: One commenter encouraged CMS to study the effects of SDS factors and incorporate appropriate risk-adjustments on all proposed measures in the Hospital IQR Program in order for results to accurately reflect the differences in patients treated in hospitals. The commenter also specifically requested that the following measures be assessed for the impact of SDS factors: Kidney/UTI Clinical Episode-Based Payment measure; Cellulitis Clinical Episode-Based Payment measure; Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure; Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment measure; Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA; Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction; Excess Days in Acute Care after Hospitalization for Heart Failure; Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization Measure, and the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization Measure.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures. To date, we have found that hospitals that care for large proportions of patients of low sociodemographic status are capable of performing well on our measures (we refer readers to the 2014 Chartbook pages 48–57, 70–73, and 78 at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*).

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We discuss specific comments and our finalized policies for each of the proposed measures below.

[147] MAP's ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' January 2015 *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.*

[148] *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy-Goals.pdf.*

a. Hospital Survey on Patient Safety Culture

(1) Background

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24566 through 24567), for the FY 2018 payment determination and subsequent years, we proposed to adopt the Hospital Survey on Patient Safety Culture. This proposed structural measure assesses whether a hospital administers a patient safety culture survey. Improving the safety of patient care is a priority and a quality improvement goal for CMS. We believe this structural measure will allow us to gain an understanding of whether hospitals are using a survey of patient safety culture in their hospitals. Because the number of questions in this measure is limited to five and can be completed using a Web-based tool, we believe this structural measure will not add undue reporting burden to hospitals.

We note that patient safety culture surveys are useful tools for measuring organizational conditions that can lead to adverse events and other incidences that can cause harm to patients in health care organizations.[149] Patient safety culture surveys can be used to: (1) Raise staff awareness about patient safety; (2) assess the current status of patient safety culture; (3) identify strengths and areas for improvement; and (4) examine trends in patient safety culture over time.[150]

There are multiple surveys that are currently used by the healthcare industry to assess patient safety culture including: The Pascal Metrics' Safety Attitudes Questionnaire (SAQ);[151] the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture (HSOPSC);[152] the Patient Safety Climate in Healthcare Organizations (PSCHO);[153] and the Manchester Patient Safety Framework.[154] However, it is not clear which patient safety culture survey is used most frequently, or how many hospitals consistently assess their performance on these surveys. One example of use of a patient safety culture survey is the HSOPSC, which is nonproprietary and available to hospitals at no cost. AHRQ developed the survey, with CMS input, released it in 2004, and subsequently displayed results from 653 hospitals in 2014.[155] Use of the HSOPSC, as well as reporting results to AHRQ, was and continues to be voluntary. Among the reporting hospitals, there was variation in frequency of survey use, format of administration (Web versus paper) and staff sampling scheme.[156]

Through the proposed Hospital Survey on Patient Safety Culture Measure, we will begin to understand how hospitals are using surveys, like the examples cited above, in improving their patient safety culture. This proposed measure will allow CMS to collect data on whether a hospital conducts a patient safety culture survey, and if so, which tool they use, how frequently the tool is administered, and the response rate. This structural measure will help inform CMS of whether a measure targeting the culture of patient safety using a specific survey is feasible.

Finally, we note that the MAP supports this measure and specifically highlighted that a patient safety culture survey is an important tool for hospitals to use to build a system of quality improvement within health care facilities.[157] While this measure is not currently NQF-endorsed, we proposed this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this final rule. We considered other existing measures related to patient safety that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess a patient safety culture, and found no other feasible and practical measures on this topic. We also are not aware of any other measures that assess whether a hospital administers a survey on patient safety.

(2) Overview of Measure

Reporting on a patient safety culture survey involves providing answers to the following questions listed below. Hospitals would submit answers via a Web-based tool on the QualityNet Web site:

(A) Does your facility administer a detailed assessment of patient safety culture using a standardized collection protocol and structured instrument?

(B) What is the name of the survey that is administered?

(C) How frequently is the survey administered?

(D) Does your facility report survey results to a centralized location? (Optional response options include the following: National data repository; state-based data repository; health system repository; other; and do not report the data outside the facility.)

(E) During the most recent assessment:

(a) How many staff members were requested to complete the survey?

(b) How many completed surveys were received?

(These questions can allow calculation of a response rate.)

(3) Data Sources

For FY 2018 payment determination and subsequent years, we proposed that data collection for this structural measure for hospitals occur from January 1 through December 31 of each calendar year, with data submission occurring the following year. For the first year, data collection would be from January 1, 2016 through December 31, 2016. These data will be collected via a Web-based tool available on the QualityNet Web site.

We invited public comment on our proposal to adopt the Hospital Survey on Patient Safety Culture measure for the FY 2018 payment determination and subsequent years.

Comment: Several commenters supported the adoption of the Hospital Survey on Patient Safety Culture within the Hospital IQR Program, stating their approval of a tool that could improve a culture of safety in hospitals. One commenter recommended that CMS leverage the findings from this measure to identify a consistent tool for measuring this attribute in future proposals. One commenter noted that a safety culture survey allows hospitals to

[149] Nieva VF, Sorra J.: *Safety culture assessment: a tool for improving patient safety in healthcare organizations.* Qual Saf Health Care 2003; 12:ii17–23.

[150] Frequently Asked Questions: Surveys on Patient Safety Culture. October 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/pscfaq.html.*

[151] Survey. (n.d.). Available at: *http://www.pascalmetrics.com/solutions/survey/.*

[152] Hospital Survey on Patient Safety Culture. (n.d.). Available at: *http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html.*

[153] Measurement Instrument Database for the Social Sciences. (n.d.). Available at: *http://www.midss.org/content/patient-safety-climate-healthcare-organizations-pscho.*

[154] Dianne, P. (n.d.). Manchester Patient Safety Framework (MaPSaF). National Patient Safety Agency. Available at: *http://www.nrls.npsa.nhs.uk/resources/?entryid45=59796.*

[155] Hospital Survey on Patient Safety Culture: 2014 User Comparative Database Report: Executive Summary. March 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/2014/hosp14summ.html.*

[156] Hospital Survey on Patient Safety Culture: 2014 User Comparative Database Report: Executive Summary. March 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/2014/hosp14summ.html.*

[157] National Quality Forum Measure Application Partnership. ''Spreadsheet of MAP 2015 Final Recommendations.'' Available at: *http://www.qualityforum.org/map/.*

identify gaps in patient safety, build awareness of critical issues, and examine trends in patient safety trends over time.

Response: We thank the commenters for their support. The purpose of this measure is to obtain comprehensive information on which surveys are being utilized from all hospitals eligible to report under the Hospital IQR Program. We hope to obtain valuable information from the structural measure that can assist us in assessing the feasibility of implementing a single survey on patient safety culture in the future. We note that patient safety culture surveys are useful tools for measuring organizational conditions that can lead to adverse events and other incidences that can cause harm to patients in health care organizations. Improving the safety of patient care is a priority and a quality improvement goal for CMS.

Comment: Several commenters noted that they are not confident that the measure will add value to the Hospital IQR Program because it assesses whether hospitals utilize a patient safety culture survey but does not actually assess a hospital's culture. The commenters recommended that CMS focus on development measures for patient safety outcomes.

Response: The purpose of this measure is to obtain comprehensive information on which surveys are being utilized from all hospitals eligible to report under the Hospital IQR Program. While we agree with the commenters that this particular measure does not assess the safety cultures of hospitals, this measure will provide us with more information on whether there is widespread use of a single survey on patient safety culture and inform future measure development activities.

Comment: One commenter expressed concern that the use of this measure will burden hospitals by increasing administrative costs associated with survey implementation and evaluation.

Response: We are clarifying that the adoption of this structural measure is not mandating the use of a specific patient safety culture survey or one at all; the purpose is to obtain comprehensive information on which, if any, surveys are being utilized from all hospitals eligible to report under the Hospital IQR Program. For hospitals that do not currently have a survey in place, they would simply respond that they do not administer a detailed assessment of patient safety culture using a standardized collection protocol or structured instrument (the first question in the Overview of Measure section), and leave the rest of the questionnaire blank.

Comment: Some commenters recommended that CMS refrain from making the Patient Safety Culture survey data immediately publicly available. The commenters expressed concern that because it is not established which survey is associated with higher quality, displaying data on this measure may be misleading to beneficiaries.

Response: We disagree with commenters that posting data about this measure should be delayed on the *Hospital Compare* Web site. Beneficiaries would not be misled by the posted information. Data displayed on *Hospital Compare* for this measure would not link the use of a specific survey with higher quality. The purpose of this measure is to obtain comprehensive information on whether hospitals are using a survey and which surveys are being utilized.

Comment: Some commenters opposed the Hospital Survey on Patient Safety Culture measure, and recommended that CMS should obtain this information from other sources, such as Partnership for Patients. The commenters also believed that this survey does not provide CMS with data on a particular patient safety culture survey that CMS could require in the future.

Response: The purpose of this measure is to obtain comprehensive information on whether hospitals are using surveys and which surveys are being utilized from all hospitals eligible to report under the Hospital IQR Program. The goal is to assess the landscape of which surveys are currently used. The Partnership for Patients' Organizational Assessment Tool (OAT) [158] does not collect information on specific surveys utilized by hospitals or particularly those participating in the Hospital IQR Program, which is our main purpose for adopting this measure.

Comment: Some commenters expressed concern that the Patient Safety Culture Measure is not NQF-endorsed.

Response: As stated above in our measure discussion, we note that the MAP supports this measure and specifically highlighted that a patient safety culture survey is an important tool for hospitals to use to build a system of quality improvement within health care facilities.[159] While this measure is not NQF-endorsed, we proposed this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this final rule. We considered other existing measures related to patient safety that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess a patient safety culture, and found no other feasible and practical measures on this topic. We also are not aware of any other measures that assess whether a hospital administers a survey on patient safety.

This structural measure will allow us to assess whether hospitals are using surveys, which surveys are being utilized, and the frequency of their use. This information will assist us in assessing the feasibility of implementing a single survey on patient safety culture in the future.

Comment: One commenter recommended that CMS consider a metric in which hospital survey scores are indicated and noted that a climate survey measure may be more appropriate than a culture survey measure.

Response: We thank the commenter for its recommendations. This structural measure will allow us to assess whether and which patient safety culture surveys are being utilized by hospitals and the frequency of their use. This is a necessary first step in determining whether a single survey could be implemented in the future, such as one in which hospital survey scores are indicated. Furthermore, the terms ''climate survey'' and ''culture survey'' tend to be used interchangeably, thus, making it difficult to assess which climate surveys are not already considered culture surveys. In addition, we were unable to identify any NQF-endorsed measures that assess a patient safety climate.

Comment: One commenter recommended that CMS focus on patient safety measures addressing falls as well as nurse staffing and skill mix.

Response: We disagree that we should only focus on patient safety measures that address falls and nurse staffing and skill mix. This structural measure will allow us to assess whether and which patient safety culture surveys are being utilized by hospitals and the frequency of their use. We note that some surveys, such as the AHRQ Hospital Survey on Patient Safety Culture, include a staffing assessment.

Comment: One commenter expressed concern that structural measures do not provide meaningful differences in the

[158] Organizational Assessment Tool retrieved from *http://partnershipforpatients.cms.gov/p4p_resources/organizational-assessment-tool/organizationalassessmenttool.html*.

[159] National Quality Forum Measure Application Partnership. ''Spreadsheet of MAP 2015 Final Recommendations.'' Available at: *http://www.qualityforum.org/map/*.

quality of care for patients and urged CMS to provide hospitals more information on the time period for conducting such a survey.

Response: Structural measures may be perceived as not providing meaningful differences in quality of care since, many times, these types of measures request information on whether a hospital is participating in or utilizing a registry or checklist, which is then displayed on *Hospital Compare* as a ''yes'' or ''no.'' However, we believe registries can provide meaningful feedback to hospitals to improve their practices, and a safe surgery checklist is considered a best practice.[160] At this time, we have not determined how many years we will keep this measure in the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing the adoption of the Hospital Survey on Patient Safety Culture measure for the FY 2018 payment determination and subsequent years as proposed.

b. Clinical Episode-Based Payment Measures

(1) Background

Clinical Episode-Based Payment measures are clinically coherent groupings of healthcare services that can be used to assess providers' resource use. Combined with other clinical quality measures, they contribute to the overall picture of providers' clinical effectiveness and efficiency. Episode-based performance measurement allows meaningful comparisons between providers based on resource use for certain clinical conditions or procedures, as noted in the NQF report for the ''Episode Grouper Evaluation Criteria'' project available at: *http://www.qualityforum.org/Publications/2014/09/Evaluating_Episode_Groupers__A_Report_from_the_National_Quality_Forum.aspx*) and in various peer-reviewed articles.[161] Episode-based measurement further supports CMS' efforts in response to the mandate in section 3003 of the Affordable Care Act that the Secretary develop an episode grouper to improve care efficiency and quality.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24567 through 24572), we proposed four Clinical Episode-Based Payment measures for inclusion in the Hospital IQR Program beginning with the FY 2018 payment determination: The Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure, the Cellulitis Clinical Episode-Based Payment measure, the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure, and the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure. The proposed measures evaluate the difference between observed and expected episode cost at the episode level before comparing at the provider level.

The MAP conditionally supported these measures pending NQF endorsement.[162] Once the call for measures for the Cost and Resource Use project at NQF is announced, these measures will be submitted for endorsement.

The measures we proposed are described below, and detailed specifications can be found in the ''Measure Methodology'' report for proposed episodic payment measures, available at: *http://www.qualitynet.org > Hospital-Inpatient > Claims-Based Measures > Proposed episodic payment measures > Measure Methodology.* The measures follow the general construction of the previously adopted, NQF-endorsed, Hospital IQR Program measure, Payment-Standardized Medicare Spending per Beneficiary (MSPB), described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626) and include standardized payments for Medicare Part A and Part B services.[163] Similar to the MSPB measure, the episodes are risk adjusted for individual patient characteristics and other factors (for example, attributes of inpatient stays). Unlike the MSPB measure however, these clinical episode-based measures include only Medicare Part A and B services that are clinically related to the triggering diagnosis or procedure.

Mathematically, the methodology described below first computes the provider's Episode Amount (calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost) and then divides the provider's Episode Amount by the episode-weighted median of all providers' Episode Amounts (as shown in equation (A) below).

$$\text{(A)}\ \textit{Episode Measure}_j = \frac{\textit{Episode Amount}_j}{\substack{\textit{Episode-Weighted} \\ \textit{Median of All Providers'} \\ \textit{Episode Amounts}}} = \frac{\frac{\Sigma_{i \in j}(\frac{O_{ij}}{E_{ij}})}{n_j} * \bar{O}_{i \in I}}{\substack{\textit{Episode-Weighted} \\ \textit{Median of All Providers'} \\ \textit{Episode Amounts}}}$$

where

O_{ij} = observed episode cost for episode *i* in provider *j,*

E_{ij} = expected episode cost for episode *i* in provider *j,*

$\bar{O}_i\varepsilon_I$ = average observed episode cost across all episodes *i* nationally, and

n_j = total number of episodes for provider *j.*

This methodology builds on that which was submitted to the MAP, in response to MAP feedback, and in order to yield a national episode-weighted measure. We proposed these Clinical Episode-Based Payment measures because they meet the following episode selection criteria we established for the purpose of selecting the best conditions and procedures to begin with, for Clinical Episode-Based Payment measures: (1) The condition constitutes a significant share of Medicare payments and potential savings for hospitalized patients during and surrounding a hospital stay; (2) there was a high degree of agreement among clinical experts consulted for this project that standardized Medicare payments for services provided during

[160] For example: De Vries et al. (2010). Effect of a Comprehensive Surgical Safety System on Patient Outcomes. *The New England Journal of Medicine, 363,* 1928–1937. DOI: 10.1056/NEJMsa0911535. Available at *http://www.nejm.org/doi/full/10.1056/NEJMsa0911535.* ''WHO Guidelines for Safe Surgery'' available at: *http://whqlibdoc.who.int/publications/2009/9789241598552_eng.pdf.*

[161] For example: Hussey, P. S., Sorbero, M. E., Mehrotra, A., Liu, H., & Damberg, S. L.: (2009). Episode-Based Performance Measurement and Payment: Making It a Reality. *Health Affairs, 28*(5), 1406–1417. Doi:10.1377/hlthaff.28.5.1406.

[162] National Quality Forum. The report is available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx* and the ''Spreadsheet of MAP 2015 Final Recommendations'' is available at: *http://www.qualityforum.org/map/.*

[163] Detailed measure specifications can be found in the ''Medicare Spending Per Beneficiary (MSPB) Measure Overview,'' available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

this episode can be linked to the care provided during the hospitalization; (3) episodes of care for the condition are comprised of a substantial proportion of payments and potential savings for postacute care, indicating episode payment differences are driven by utilization outside of the MS–DRG payment; (4) episodes of care for the condition reflect high variation in post-discharge payments, enabling differentiation among hospitals; and (5) the medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioners.

We discuss measure-specific comments after each measure discussion. However, because many comments apply to all of the proposed Clinical Episode-Based Payment measures, a discussion of comments that are not measure-specific can be found after the measure discussions.

(2) Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure have high costs with substantial variation. In CY 2012, Medicare FFS beneficiaries experienced over 234,000 kidney/urinary tract infection episodes triggered by related inpatient stays.[164] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled more than $2.5 billion in 2012, with an average episode cost of over $10,000. There is substantial variation in kidney/urinary tract infection episode costs—ranging from approximately $4,800 at the 5th percentile to approximately $27,000 at the 95th—that is driven by variation in post-discharge costs clinically-related to the inpatient hospitalization. These clinically-related post-discharge costs are an indicator of the quality of care provided during the hospitalization.

The MAP conditionally supported this measure pending NQF review and endorsement. Members noted that this measure addresses the cost of care for common conditions, but other members expressed caution that the most efficient providers may reduce overall hospitalizations and that the remaining hospitalizations may be a biased sample for measuring performance across providers. In response to this concern, we note that this measure is limited by design to the inpatient hospital, which means that resource use is evaluated only for patients that have been hospitalized for the episode condition, and providers are evaluated relative to other providers treating hospitalized patients. To address the concern that providers involved in the hospitalization of only the most complex cases might be disadvantaged under the measure, we note that the episode is risk-adjusted to account for differences in patient characteristics that may affect costs, such that expected costs for more complex patients will be higher and expected costs for less complex patients will be lower. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement.

We proposed this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this final rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess kidney/urinary tract infection. We also are not aware of any other measures that assess kidney/urinary tract infection treatment efficiency and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including postacute care) a kidney/urinary tract infection-related hospital admission. This measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window''). In contrast to the MSPB measure, however, this measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS–DRG that identifies a kidney/urinary tract infection.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. The period of performance for the measure is 1 year, beginning with CY 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A kidney/urinary tract infection episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS–DRG that indicates a kidney/urinary tract infection. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this final rule.

We invited public comment on our proposal to adopt the Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

Comment: One commenter opposed the proposed addition of the Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure and noted that it may be more appropriate in an outpatient setting. The commenter noted that kidney and urinary tract infection is often seen with comorbidities, resulting in a more severe episode of care. The commenter

[164] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.*

suggested that the measure be limited to a more specifically defined set of patients so that comparisons can be made.

Response: We appreciate the commenter's concerns about the variety of clinical conditions associated with kidney and urinary tract infection. With regard to the suggestion that the measure should be limited to the outpatient setting, we believe that this measure is appropriate for the hospital inpatient setting, because it does not include all cases of kidney/urinary tract infection, but rather, are limited to cases with infections whose severity required admission to a hospital. We also believe that risk adjustment will account for the heterogeneity present among patients hospitalized with kidney and urinary tract infections. The risk adjustment model includes demographics (for example, age) and a range of health conditions that are clinically related to kidney/urinary tract infections: Diabetes, end-stage renal disease, and paralysis (which may be associated with neurogenic bladder), among others. Furthermore, services grouped to the episode are limited to those that are directly related to the episode condition. Creation of this episode was based on the observation that significant costs are associated with this condition.

Comment: One commenter expressed concern about how hospitals can determine when a kidney/urinary tract infection begins, which determines whether an index admission is triggered for the episode.

Response: Because this measure begins with a hospital admission for a kidney/urinary tract infection, the episode is triggered by the admission. Only infections that were serious enough to require hospitalization are included.

Comment: One commenter supported the proposal to include the Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure, on the condition that the methodology is tested and validated.

Response: We appreciate the commenter's support. The methodology has been tested on the population of 2012 Medicare beneficiaries. The testing was conducted with Medicare claims data and is therefore, expected to be valid. Historically, the NQF has found Medicare claims-based measures, such as the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789), to be valid. For this all-cause readmission measure, 'reliability and validity [at the data element level and at the measured score level] was generally received as adequate by the steering committee' (NQF: 2012 Proc. Feb 2012, available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70455*).

The proposed Clinical Episode-Based Payment measures' episodes were created using the methodology for grouping treatment and post-discharge services as well as the risk adjustment model all outlined in the supplemental documentation for the FY 2016 IPPS and LTCH Prospective Payment System Proposed Rule available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*. After episodes were constructed, medical services grouped to the episodes were validated by a team of clinicians with expertise in Medicare claims data. However, in response to comments, we will give hospitals an opportunity to validate data included in the episodes during review of the confidential hospital-specific feedback reports discussed in more detail below.

(3) Cellulitis Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Cellulitis Clinical Episode-Based Payment measure have high costs with substantial variation. In CY 2012, Medicare FFS beneficiaries experienced more than 143,000 cellulitis episodes triggered by related inpatient stays.[165] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled more than $1.4 billion in 2012, with an average episode cost of approximately $10,000. There is substantial variation in cellulitis episode costs—ranging from about $5,000 at the 5th percentile to about $24,000 at the 95th—that is driven by variation in post-discharge costs clinically-related to the inpatient hospitalization. These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization.

The MAP conditionally supported this measure pending NQF review and endorsement. Members noted that this measure addresses the cost of care for an important condition. Other members expressed caution on the use of this measure noting that cellulitis is a highly variable condition that may be challenging to measure using an episode-based framework. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement. We note that there is substantial variation in cellulitis episode costs that is driven by variation in post-discharge costs clinically-related to the inpatient hospitalization. This variation suggests that there may be opportunity to improve the efficiency of care for cellulitis treatment.

We proposed this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this final rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess cellulitis. We also are not aware of any other measures that assess cellulitis treatment efficiency, and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Cellulitis Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including post-acute care) a cellulitis-related hospital admission. The Cellulitis Clinical Episode-Based Payment measure, like the MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window''). In contrast to the MSPB measure, the Cellulitis Clinical Episode-Based Payment measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Cellulitis Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS–DRG that identifies cellulitis.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during this episode window and

[165] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. The period of performance is one year, beginning with calendar year 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A cellulitis episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS–DRG that indicates cellulitis. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this final rule.

We invited public comment on our proposal to adopt the Cellulitis Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

Comment: A few commenters opposed the proposed addition of the Cellulitis Clinical Episode-Based Payment measure and recommended that it may be more appropriate as an outpatient cost measure because treatment for cellulitis can largely be handled in the outpatient setting. The commenters also noted that patients with cellulitis often have comorbidities that might make it difficult to group all cellulitis patients together. One commenter specifically expressed concern that the cellulitis measure does not adequately capture differences in acute and chronic cellulitis.

Response: We appreciate the commenter's concerns about the variety of clinical conditions associated with cellulitis. With regard to the suggestion that the measure would be better suited to an outpatient setting, we believe that this measure is appropriate for the hospital inpatient setting, because it does not include all cases of cellulitis. Rather, it is limited to either an exacerbation or acute flare of cellulitis whose severity requires admission to a hospital. Whether the cellulitis is chronic or acute, the design of the episode measure, which is limited to the inpatient hospitalization and the immediate follow-up period, allows for meaningful comparison across providers. Hospitalized cellulitis patients, with more serious soft tissue infections, are clinically distinct from patients who can be treated in other Medicare settings.

Furthermore, we do not agree that comorbidities might make it difficult to group all cellulitis patients together. The episode measure contains three clinical subtypes to address the heterogeneity present among beneficiaries hospitalized for this condition: (1) Cellulitis as a complication of diabetes; (2) cellulitis as a complication of decubitus pressure ulcers; and (3) other cellulitis. We note that beneficiaries with ulcers were not compared to beneficiaries with uncomplicated cellulitis. This breakdown creates more cohorts of beneficiaries for comparison. Risk adjustment is also applied to account for other comorbidities and complex issues in cellulitis patients. Finally, the episode focuses only on care that is directly related to those infections. The high frequency of cellulitis episodes highlights the importance of creating a measure for this condition.

(4) Gastrointestinal (GI) Hemorrhage Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Gastrointestinal (GI) Hemorrhage Clinical Episode-Based Payment measure have high costs with substantial variation. In calendar year 2012, Medicare FFS beneficiaries experienced 181,646 GI hemorrhage episodes triggered by related inpatient stays.[166] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled nearly $2 billion in 2012, with an average episode cost of about $11,000. There is substantial variation in GI hemorrhage episode costs—ranging from approximately $6,500 at the 5th percentile to approximately $23,000 at the 95th—that is driven by variation in post-discharge costs clinically related to the inpatient hospitalization. These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization. For the purposes of reporting, and as suggested by the MAP, the GI hemorrhage episodes may be split into those treating an upper GI bleed and those treating a lower GI bleed due to clinical differences in patterns of care for those treatments. More information can be found in the supplemental documentation for the FY 2016 IPPS and LTCH Prospective Payment System Proposed Rule available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

The MAP conditionally supported this measure pending NQF review and endorsement. MAP members noted that this measure addresses the cost of care for GI bleeding. Several members expressed caution that the most efficient providers may reduce overall hospitalizations thus those inpatient hospitalizations that remain are a biased sample for measuring performance across providers. In response to these concerns, we note that this measure is limited by design to GI hemorrhage episodes treated in the inpatient hospital, which means that resource use is evaluated only for patients that have been hospitalized for the episode condition, and providers are evaluated relative to other providers treating hospitalized patients. With regard to the concern that efficient providers may reduce hospitalizations, leaving a biased sample of less efficient providers, we note that the episode is risk-adjusted to account for differences in patient characteristics that may affect costs, thus to the extent that variation in treatment prior to hospitalization results in patterns of sicker (or healthier) GI hemorrhage patients admitted to certain hospitals, risk adjustment addresses these differences. For example, for providers who admit comparatively less complex patients to the inpatient hospital for treatment of GI bleeds, risk adjustment would cause their expected costs to be lower. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement.

We proposed this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this final rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed

[166] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

measures that assess GI hemorrhage. We also are not aware of any other measures that assess GI hemorrhage treatment efficiency, and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including postacute care) a gastrointestinal hemorrhage-related hospital admission. This measure, like the MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window''). In contrast to the MSPB measure, the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS–DRG that identifies a gastrointestinal hemorrhage.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. The period of performance is 1 year, beginning with CY 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A gastrointestinal hemorrhage episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS–DRG that indicates gastrointestinal hemorrhage. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this final rule.

We invited public comment on our proposal to adopt the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

Comment: One commenter supported CMS' proposed inclusion of Gastrointestinal Hemorrhage as part of the Clinical Episode-Based Payment measures and agreed that post-discharge care costs drive variation in spending for this condition.

Response: We thank the commenter for its support.

Comment: One commenter opposed the proposed addition of the GI Hemorrhage Clinical Episode-Based Payment measure, noting that the many conditions and medical situations may cause GI hemorrhage, and that these different conditions and causes cannot be compared against each other. The commenter suggested that the measure be limited to a more specifically defined set of patients so that comparisons can be made.

Response: We appreciate the commenter's opinion that GI hemorrhage is a broad category. Rather than limit the patient set, and consequently the number of beneficiaries whose care could be captured in the measure, we have broken the overall measure down into clinical subtypes, which allows comparison among clinically similar beneficiary groups. This allows meaningful comparison of patients who have similar conditions and causes for GI hemorrhage. The measure, as it was proposed, includes four clinical subtypes for the GI bleed episode measure: (1) Upper GI bleeds; (2) lower GI bleeds; (3) upper and lower GI bleeds; and (4) GI bleeds of unknown source. Specifications can be found in the ''Measure Methodology'' report link found in section VIII.A.7.b.(7)(B) of the preamble of this final rule.

Furthermore, we believe that risk adjustment will account for other health and demographic factors that may impact a beneficiary's episode costs. Risk adjustment factors in age, 70 severity of illness measures, and comorbidities that may affect a GI hemorrhage episode: Diabetes, inflammatory bowel disease, hematological disorders, drug and alcohol dependence, liver cirrhosis, and intestinal obstruction/perforation, among others. The data showed that there was sufficient similarity in the experiences of these patients that episodes could be created. In selecting post-discharge services to group to the episode, clinicians focused on care that was directly related to the bleeding. Care was taken at this time to group only services that had a direct connection to the bleed that triggered the episode.

(5) Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Spinal Fusion/Refusion Clinical Episode-Based Payment measure have high costs with substantial variation. In CY 2012, Medicare FFS beneficiaries experienced about 69,000 spinal fusion/refusion episodes triggered by related inpatient stays.[167] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled more than $2.6 billion in 2012, with an average episode cost of approximately $38,000. There is substantial variation in spinal fusion/refusion episode costs—ranging from approximately $28,000 at the 5th percentile to approximately $60,000 at the 95th—that is driven by variation in post-discharge costs clinically related to the inpatient hospitalization. These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization.

The MAP conditionally supported this measure pending NQF review and endorsement. Some members raised concerns that patients with cancer should be excluded from this measure. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement. We note that this measure is titled ''Spine Fusion/Refusion Clinical Episode-Based Payment measure'' in the MAP spreadsheet. In addition, the episode is risk-adjusted to account for differences in patient characteristics, including the presence of cancer in the patient's

[167] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.*

history, which may affect costs but are outside of providers' control.

We proposed this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this final rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess spinal fusion/refusion. We also are not aware of any other measures that assess spinal fusion/refusion treatment efficiency, and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including postacute care) a lumbar spine fusion/refusion-related hospital admission. The Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure, like the MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window''). In contrast to the MSPB measure, the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS–DRG and ICD–9–CM procedure code that identify a lumbar spine fusion/refusion.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. The period of performance is 1 year, beginning with calendar year 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A lumbar spine fusion/refusion episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS–DRG and ICD–9 Procedure code that indicate lumbar spine fusion/refusion. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this final rule.

We invited public comment on our proposal to adopt the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

Comment: One commenter supported CMS' proposed inclusion of Lumbar Spine Fusion/Refusion as part of the Episode-based-payment measures and agreed that post-discharge care costs drive variation in spending for this condition.

Response: We thank the commenter for its support.

Comment: A few commenters opposed the proposal to include the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure, noting that refinements would be required, in order to account for patient variability and to ensure that surgeons are measured appropriately and also that stratification is needed to distinguish between elective surgery and emergency surgery, which is often more complex.

Response: We appreciate the commenters' concerns and feedback from clinicians and specialty groups during this process. Upon further analysis, we agree that additional refinements, potentially including stratification or other specification to address differences in reasons for surgery (for example, elective vs. emergency), are needed for this measure to account for the variety of patient clinical presentations that could comprise the lumbar spine fusion/refusion measure and to ensure that hospitals are measured appropriately. Specifically, unlike the clinical subtypes in the Cellulitis and GI Hemorrhage Clinical Episode-Based Payment measures, we agree that the procedure codes included in each subtype of the proposed Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure are too broad and do not adequately account for the heterogeneity present among the population of beneficiaries who experience episodes for the measure. We note that the measure as proposed would measure hospitals, not individual surgeons, in the context of the Hospital IQR Program.

Therefore, in response to commenters' concerns regarding the heterogeneity of the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure, we are not finalizing it for the Hospital IQR Program at this time. We will continue development of this measure, and if after further refinement and discussion with clinical experts we believe the measure should be included in the Hospital IQR Program, we would propose the measure again through future rulemaking.

Comment: Some commenters expressed concern that the proposed Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure may assess variations in cost that are caused by factors outside of providers' control, such as the quality of post-discharge care to which a patient has access. The commenters also expressed concern that the measure may incentivize providers to avoid certain post-discharge costs, such as those associated with imaging, and that the lower costs achieved may not reflect quality.

Response: This measure, like the other Clinical Episode-Based Payment measures, is payment-standardized and risk-adjusted to remove differences in Medicare payment policy and patient health status that can affect episode costs but are outside the control of the provider managing the episode. Payments are standardized to eliminate geographic differences and special program payments unrelated to resource use, such as disproportionate share hospital (DSH) payments. Payment standardization assigns a standardized allowed amount for each service to facilitate comparison across providers. Outliers in cost are also subject to clinical review to further understand these cases.

Currently, the risk adjustment used for these measures is the same as that of the NQF-endorsed MSPB measure (NQF #2158). Therefore, providers and hospitals that treat patients with greater complexity will be accounted for through payment standardization and risk adjustment.

As the commenters noted, the quality of post-discharge care can affect the

hospital's performance on the measure; therefore, hospitals involved in the provision of high-quality inpatient care as well as appropriate discharge planning and post-discharge care coordination would be expected to perform well on this measure. We believe that inclusion of other costs, such as those for post-discharge care is imperative to incentivizing improved care coordination and care transitions. We disagree that such costs are outside of the hospitals' control. While the quality of post-discharge care may affect the measure, we believe that hospitals are in a position to influence the post-discharge experience and outcomes, which in turn impact costs, for the patients they serve.

With regard to the comments that the measure might incentivize hospitals to avoid needed post-discharge care and that lower cost does not necessarily indicate better quality, we note that this measure was proposed as one measure within the Hospital IQR Program, which includes numerous measures spanning various aspects of hospital quality. In addition to our belief that hospitals are interested in providing the best and most appropriate care for the Medicare beneficiaries they serve, cost measures are balanced by a wide array of quality measures. We do not believe that a hospital would avoid providing needed care (and forego the associated Medicare payments for such services), in the interest of improving performance on one payment measure. Rather, we believe that Clinical Episode-Based Payment measures incentivize hospitals to look for opportunities to gain efficiencies, avoid unnecessary services, which represent poor quality, and avoid unnecessary re-hospitalizations.

However, as discussed above in response to comments concerning the heterogeneity of the universe included in the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure, we are not finalizing it for the FY 2018 payment determination and subsequent years for the Hospital IQR Program as proposed.

(6) Inclusion and Exclusion Criteria

A full list of the MS–DRG codes used to identify beneficiaries included in the final cohort for each of the proposed episode-based payment measures can be found in the ''FY 2016 IPPS NPRM Episode Supplemental Documentation'' report in the ''Downloads'' section at: ''NPRM Episode Supplemental Documentation'' report at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

The exclusion methodology applied to each of these measures is the same as the one used to calculate the previously adopted NQF-endorsed MSPB measure (NQF #2158) described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626) and available in the ''MSPB Measure Information Form'' at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350*. Episodes for beneficiaries that meet any of the following criteria are excluded from the measure:

- Lack of continuous enrollment in Medicare Parts A and B from 90 days prior to index admission through the end of the episode with Medicare as the primary payer.
- Death date during episode window.
- Enrollment in Medicare Advantage during the episode window.

In addition, claims that meet any of the following criteria do not trigger, or open, an episode:

- Claims with data coding errors, including missing date of birth or death dates preceding the date of the trigger event.
- Claims with payment ≤ 0.
- Acute inpatient stays that involved a transfer.
- Claims from a non-IPPS or non-subsection (d) hospital.

Claims that meet the following criterion will not be included in an episode:

- Claims with payment ≤ 0.

(7) Standardization and Risk-Adjustment

(A) Standardization

Standardization, or payment standardization, is the process of adjusting the allowed charge for a Medicare service to facilitate comparisons of resource use across geographic areas. Medicare payments included in these proposed episode-based measures would be standardized according to the standardization methodology previously finalized for the Hospital IQR Program MSPB measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626) and used for all of the payment measures included in the Value-Based Payment Modifier Program. The methodology removes geographic payment differences, such as wage index and geographic practice cost index, incentive payment adjustments, and other add-on payments that support broader Medicare program goals, such as add-on payments for indirect graduate medical education (IME) and add-ons for serving a disproportionate share of uninsured patients (DSH).

(B) Risk Adjustment

Risk adjustment uses patient claims history to account for case-mix variation and other factors. The steps used to calculate risk-adjusted payments align with the NQF-endorsed MSPB measure (NQF #2158) method as specified in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51626). Specifications for the risk-adjustment employed in the proposed episode-based payment measures are included in the ''FY 2015 IPPS NPRM Episode Supplemental Documentation'' report, Section 4, titled ''Calculating the Hospital-Based Episode Measure,'' which can be found in the ''FY 2016 IPPS NPRM Episode Supplemental Documentation'' report at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

We invited public comment on our proposals.

Comment: Some commenters suggested that the risk adjustment of these measures is not sufficient and recommended a risk adjustment model that is validated and tested before measure implementation. One commenter further suggested that the risk adjustment model cannot be sufficiently determined from claims data.

Response: We disagree with the comment that Medicare claims data is insufficient for the purpose for risk adjustment. Using the diagnosis codes billed on Medicare claims, each episode's costs are risk adjusted to account for differences in patient characteristics (such as the presence of certain comorbidities) that may affect costs. With regard to the comment that the risk adjustment methodology is insufficient, or that it has not been tested and validated, we disagree. The risk adjustment construct used is the same as the NQF-endorsed MSPB measure's risk adjustment model (NQF #2158). The MSPB model has been validated, tested, and NQF endorsed. We refer readers to *http://www.qualityforum.org/QPS/2158* for more information on the MSPB's risk adjustment model.

Comment: One commenter questioned whether the proposed measures would accurately reflect health disparities, which could adversely impact care.

Response: Each episode's costs are risk adjusted to account for differences in patient characteristics (such as the presence of certain pre-existing conditions) that may affect costs. This is to ensure that hospitals are not penalized for serving populations that are sicker or have higher incidences of

chronic disease. The risk adjustment method used is the same as that used for the NQF-endorsed MSPB measure (NQF #2158). The MSPB measure description, including risk adjustment information, may be found in the measure information form located on the NQF's Web site at: *http://www.qualityforum.org/QPS/2158*.

We received a number of comments on the proposed measures in general. The following comments apply to all four of the proposed episode-based payment measures.

Comment: Many commenters opposed the addition of the Clinical Episode-Based Payment measures until they are NQF-endorsed, noting that the lack of endorsement poses questions about their reliability, validity, and feasibility. Some commenters specifically noted that these measures should not be publicly reported until they are NQF-endorsed. One commenter expressed concern that there will be substantial variability in hospitals' ability to report statistically reliable information on all of the proposed measures, given variation in volume.

Response: We do not agree that these measures should not be publicly reported until they are NQF-endorsed. We work closely with the NQF on issues related to measure endorsement but, as stated in previous rulemaking (for example, 79 FR 50222), we believe that consensus among affected parties also can be reflected by other means, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. Under the authority of section 1886(b)(3)(B)(viii)(IX) of the Act, we may specify a measure that is not endorsed by NQF as long as due consideration is given to measures currently endorsed by the NQF or any other consensus organizations identified by the Secretary. We reviewed the NQF-endorsed measures, and we were unable to identify any other NQF-endorsed measures that are condition-specific episode based cost measures. We also are not aware of any other condition-specific episode based cost measures that have been endorsed or adopted by a consensus organization other than NQF.

The measures have been conditionally supported by the MAP, and the measures will be submitted to the NQF when the NQF opens a call for submission for episode-based measures. We think that these measures serve an important purpose and fill a gap in available resource use data. Public reporting will help consumers identify hospitals involved in the provision of efficient care for these conditions and procedures. In addition, public reporting is an important tool to incentivize changes in behavior and encourage hospitals to look for opportunities for improved efficiency. Further, we believe that publicly displaying measure performance data allows us to provide the desired transparency to consumers and stakeholders.

In response to commenters' concerns about validity and feasibility of the Clinical Episode-Based Payment measures, the measures follow the general construction of the previously adopted, NQF-endorsed, Hospital IQR Program measure, Payment-Standardized Medicare Spending per Beneficiary (MSPB) (NQF #2158), described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626). Similar to the MSPB measure, the Clinical Episode-Based Payment measures are constructed using Medicare Parts A and B claims data. As in the MSPB measure, these episode-based payment measures group Parts A and B payment for three days prior to hospital admission to 30 days post-discharge and utilize a risk adjustment model that includes patient characteristics along with other factors (for example, attributes of inpatient stays) similar to the MSPB measure. The successful implementation of the MSPB measure provides evidence to the feasibility of the Clinical Episode-Based Payment measures.

As we noted in the FY 2013 IPPS/LTCH PPS final rule, published research indicates that spending for an episode of care varies ''greatly'' among hospitals (N Engl J Med. 2008; 359: 3–5) and measures for which there is a larger inter-hospital variability are more likely to be reliable (77 FR 53588 through 53589). The condition-specific cost measures we proposed were selected, in part, because they represent common conditions with evidence of large variation in payments. In addition to the positive correlation between high variability and measure reliability, the selection of measures reflecting common conditions and procedures with large variation in cost encourages hospitals to work to provide higher value care where there is the most opportunity for improvement. This will allow the greatest number of patients to benefit from improvements, and will ensure the largest sample sizes to ensure reliability. Episodes were also chosen based on the ability of the initial hospital care provided for a condition or procedure to influence near-term patient outcomes. This selection criterion helps to ensure measure validity, because there is less chance that differences are due to chance, but rather, they are more likely to be due to the actions taken by the hospital. The proposed measures were fully tested and reviewed by physicians from a variety of specialties to ensure clinical validity. Data on episode cost, frequency, and variation in costs from measure testing, which reflect the validity of the measures are included in the ''Measure Methodology'' report for proposed episodic payment measures, available at: *http://www.qualitynet.org > Hospital-Inpatient > Claims-Based Measures > Proposed episodic payment measures > Measure Methodology*.

These measures are constructed using Medicare administrative claims data, which have been shown to be a reliable data element for measure construction. The NQF has found other resource use measures that are based on Medicare claims data to be reliable and valid. As one example, for the all-cause readmission measure (NQF #1789), ''reliability and validity [at the data element level and at the measured score level] was generally received as adequate by the steering committee'' (NQF, Feb. 2012: Patient Outcomes All Cause Readmissions Expedited Review Pre-voting Call Transcript), available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70455*.

Further, in a memorandum to the NQF Board of Directors, the NQF's Senior Vice President for Performance Measures report noted that the majority of NQF committee members stated that the Hospital-wide All Cause Readmission Measure was highly reliable (Burstin, June 2012: Appeal of All Cause Hospital-wide All Cause Readmission Measure), available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71272*.

Although we believe the measures to be valid and reliable, in response to comments, we will post a measure reliability analysis and propose in future rulemaking a minimum number of cases for reporting to ensure reliability of publicly-reported data, prior to public reporting of these measures.

Comment: Some commenters noted the value of seeing these claims-based cost measures and suggested that CMS provide confidential individual hospital reports in order for hospitals to better understand the data and potentially determine interventions to improve processes of care.

Response: We appreciate the general support for moving toward efficiency measures, and we acknowledge that

hospitals would benefit from the opportunity to review their results and develop a deeper understanding of the measures before the measures are publicly reported.

In response to comments, we are postponing implementation and we are finalizing these three measures for the FY 2019 payment determination and subsequent years (CY 2017 performance period and subsequent years), instead of for the FY 2018 payment determination and subsequent years (CY 2016 performance period and subsequent years) as proposed, in order to allow hospitals to gain experience with the measures through confidential feedback reports. During the interim FY 2018 payment determination (CY 2016 performance period) and prior to inclusion for public reporting, we will provide hospitals with confidential hospital-specific feedback reports and supplemental files containing performance data on the three Clinical Episode-Based Payment measures we are finalizing. We currently provide confidential hospital-specific feedback reports and supplemental files for the MSPB measure, and we intend to create similar reports and supplemental files for the three Clinical Episode-Based Payment measures. We believe that the confidential hospital-specific feedback reports and supplemental files will provide hospitals with valuable data to facilitate improvement in the efficiency of the care they provide.

Comment: Many commenters raised concerns about reporting a measure that reflects the factors that may be outside of the hospital's control, including care performed in multiple settings and the clinical preferences of physicians. In addition, the commenters noted that the measure may not account for the national variation in the mix of services and degree of integration in health care delivery. One commenter specifically recommended that adoption of these measures be delayed until physicians and all post-acute care settings are assessed using similar measures. Some commenters opposed the inclusion of the four clinical episode-based measures to the Hospital IQR Program. Specifically, these commenters believed that these measures would be better suited for Accountable Care Organizations or bundled payment programs, where they may be comparably applied across all of the relevant care settings.

Response: We appreciate the comments and seek to encourage increased care coordination across providers. We disagree that Medicare payments for services received after discharge from a hospital are outside of a hospital's control. We addressed similar comments regarding the MSPB measure (NQF #2158), which is endorsed by the NQF, in the FY 2012 IPPS/LTCH PPS final rule and reiterated those comments in the FY 2013 IPPS/LTCH PPS final rule (76 FR 51623 through 51624 and 77 FR 53586 through 53587, respectively). We continue to believe, as stated in those rules, that hospitals providing quality inpatient care, conducting appropriate discharge planning, and working with providers and suppliers on appropriate follow-up care will realize efficiencies and perform well, because the Medicare beneficiaries they serve will have a reduced need for excessive post-discharge services.

With regard to the comment that the measures do not account for the degree of health system integration, the aforementioned opportunities for hospitals to exert control over post discharge expenditure and efficiency exists, regardless of the degree of integration of a health system, and in cases where systems are not well-integrated, there may be an even greater opportunity for redesign of care processes to achieve high performance on these measures. We are even more confident now that hospitals can exert influence over post-discharge expenditures in the case of the proposed episode-based payment measures, because the services within the episodes are only those that are clinically-related to the reason for admission.

To ensure that it would be appropriate to attribute the Medicare payments included in these measures to a discharging hospital, one of the selection criteria for episode development was the degree to which the clinical experts consulted agree that standardized Medicare payments for services provided during the episode can be linked to the care provided during the hospitalization. Hospital-based providers exert influence on referrals to post-acute care and service utilization, thus linking hospitalization with near-term outcomes. Measuring national variation in service utilization for these episodes would facilitate the identification of the clinical practices and arrangements that have best outcomes and efficiency. In addition, we have selected condition-specific cost measures for common conditions with evidence of large variation in payments to encourage higher value care where there is the most opportunity for improvement, the greatest number of patients to benefit from improvements, and the largest sample size to ensure reliability.

In response to the comment that the measures do not adequately address the variation in the mix of patients for whom Medicare expenditures are captured in the proposed measures, we note that the episodes within the measures are risk-adjusted, to account for the age and severity of illness of the beneficiary. This risk adjustment methodology is the same as that used for the NQF-endorsed MSPB measure (NQF #2158) and acknowledges the differences in a given hospital's case mix, so that their performance can be compared to a national average.

Furthermore, while we agree with the commenters' views regarding the value in aligning resource use measures across settings, we disagree that the reporting of these important Medicare payment measures is not appropriate for hospital-level reporting or that they would be more appropriate in an Accountable Care Organization or bundled payments structure.

With regard to the comment that the measures should be delayed until physicians and post-acute care settings are addressed, we note that we currently have physician-based analogues of the measures in the Physician Feedback Program. While post-acute care measurement programs are under development, we will take the commenter's suggestion that similar measures should be incorporated into them under consideration. We do not believe that it would be appropriate to delay the public reporting of this valuable and actionable payment information until such time as any similar, post-acute care measures are implemented. As noted above, these measures were developed in response to hospital stakeholders' feedback that we should develop a more robust and clinically cohesive measure set for hospitals. Data for these measures were reported in the 2012 Supplemental Quality and Resource Use Reports (QRURs), which are confidential feedback reports for physicians and group practices, and will be reported again in the 2014 Supplemental QRURs (79 FR 40515). More information can be found at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html.* Including these Clinical Episode-Based Payment measures in the hospital setting provides physicians with information they need to understand their role in driving the costs of episodes captured in Medicare payment measures. Physicians and groups of physicians receive data to help them more effectively target resources to realize efficiencies in the

care they provide their patients. This understanding of actionable data will facilitate coordination between physicians and hospitals to optimize the efficiency of the care they provide to Medicare beneficiaries and other patients they serve. In addition, we will also explore the potential use of these types of measures within the Medicare Shared Savings Program in the future.

Comment: Several commenters opposed the proposal of the four Clinical Episode-Based Payment measures because of concern over the use of the measures without corresponding measures of quality. One commenter noted that the measures themselves assess only volume and do not adequately consider the quality or appropriateness of the care provided.

Response: While we agree that observation of cost alongside quality is an important concept, we believe that resource use information provides useful information for consumers and other stakeholders as they seek to make informed decisions about facilities involved in the provision of efficient care, even in the absence of a corresponding quality measure.

These measures will be displayed on *Hospital Compare* along with other quality metrics. We note that, for public reporting purposes, the measures would provide valuable information regarding the cost of care for a particular condition or procedure, which is a reflection of the efficiency of that care.

Comment: Some commenters expressed concern with the Clinical Episode-Based Payment measures because they do not provide beneficiaries with information on their own financial obligations.

Response: We appreciate the suggestion that we should evaluate beneficiary expenditures and will consider that for future reporting. The proposed measures, like the MSPB measure (NQF #2158) are calculated using Medicare allowed amounts. We believe that inclusion of Medicare allowed amounts, which include both Medicare payments and beneficiaries' deductible and coinsurance, is the most appropriate and understandable approach at this time. Beneficiary expenditures are dependent on a number of aspects, including their deductibles, copay, and secondary insurers; so evaluating beneficiary expenditures at this time would be more confusing than utilizing Medicare allowed amounts, which are standardized to allow for comparison across hospitals nationwide.

Comment: One commenter expressed concern that these measures make it difficult to monitor and improve performance concurrently.

Response: We believe the commenter is suggesting that improving performance on the measures while concurrently improving quality would be difficult, and we disagree. We believe that improvement in care quality, care coordination, and discharge planning will be reflected in improved performance on these measures; so that hospitals will concurrently improve the care provided to the beneficiaries they serve and their performance on these measures. We believe that public reporting of quality, including resource use measures, is an important tool for quality improvement. The Clinical Episode-Based Payment measures are claims-based and therefore, require no additional reporting on behalf of providers.

Comment: One commenter expressed concern that the Clinical Episode-Based Payment measures overlap with the Medicare Spending per Patient measure.

Response: We developed the proposed condition-specific measures, as intended and stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53585), in response to commenters' suggestions that CMS undertake development of a more robust efficiency measure set. Commenters had also suggested that we include only services related to the reason for admission in the MSPB measure, and we responded that determinations of clinical relatedness could be subjective and that inclusion of a broad range of services would best incentivize care coordination (76 FR 51621). As a result, we developed these Clinical Episode-Based Payment measures that include only services that are clinically related to the reason for admission. For each Clinical Episode-Based Payment measure, a panel of clinicians determined which services, when occurring in the 30 days post-discharge, could be considered clinically associated with the episode. Therefore, we believe that the condition-specific measures provide additional and more targeted information about patient care. These condition-specific measures will allow patients and payers to make more fully informed comparisons of hospitals' performance. Including condition-specific cost measures alongside the total cost MSPB measure will also provide hospitals with actionable feedback that will better equip them to implement targeted improvements in comparison to an overall cost measure alone.

Comment: One commenter advised CMS to follow the advice of the appropriate stakeholders or specialties to refine or replace the Clinical Episode-Based Payment measures.

Response: We appreciate the commenter's concerns and the valuable feedback from clinicians and specialty groups during this process. We have worked closely with clinicians and contractors experienced in health services research and payment policy to define and develop the Clinical Episode-Based Payment measures to allow patients and payers to make more fully informed comparisons of hospitals' performance. We also note that the MAP conditionally supported these measures pending NQF endorsement. Accordingly, we intend to submit the measures for NQF endorsement when a call for episode-based payment measures is opened.

Comment: One commenter supported a movement towards the use of outcome measures over process-of-care measures, but noted their preference for a broad-all condition cost measure over the proposed condition-specific episode-based payment cost measures. Specifically, the commenter noted the proposed condition-specific cost measures would have smaller numbers of hospital-specific observations than an all-condition measure, which result in more random variation without providing additional useful information. The commenter supported the presentation of condition-specific cost measures, but did not support the use of the condition-specific cost measures for inclusion in determining financial incentives.

Response: We appreciate the commenter's preference for outcome measures rather than process measures. Using outcome measures, such as rehospitalization rates, is important, but we believe that the condition-specific measures (Clinical Episode-Based Payment measures) provide additional and more targeted information about care. Unlike the Medicare Spending Per Beneficiary measure (NQF #2158), the condition-specific cost measures only include costs from services/procedures related to the condition. These condition-specific measures will allow patients and payers to make more fully informed comparisons of hospitals' performance. Including condition-specific cost measures will also provide hospitals with actionable feedback that will better equip them to implement targeted improvements versus an overall cost measure alone. As noted in previous comment responses, we developed these measures in response to commenters' suggestions that we undertake development of a more robust efficiency measure set (77 FR 53585).

Comment: One commenter recommended that CMS work to improve the predictive power of the existing MSPB, instead of adopting these measures.

Response: Using total cost measures, such as the MSPB measure, is important, but we believe that the condition-specific measures in conjunction with the MSPB measure provide additional and more targeted information about care. Unlike the MSPB measure, the condition-specific cost measures only include costs from services/procedures related to the condition. These condition-specific Clinical Episode-Based Payment measures will allow patients and payers to make more fully informed comparisons of hospitals' performance. Including condition-specific cost measures will also provide hospitals with actionable feedback that will better equip them to implement targeted improvements as compared to an overall cost measure alone. As noted in the response to previous comments, we developed these measures, as stated and planned in the FY 2013 IPPS/LTCH PPS final rule, in response to commenters' suggestions that we undertake development of a more robust efficiency measure set (77 FR 53585).

Comment: A few commenters supported the proposal to include condition-specific episodes of care measures, noting that the measures align with the National Quality Strategy and address conditions that are drivers of cost for the Medicare program. In addition, commenters noted that the addition of these measures will promote better coordination of care.

Response: We thank the commenters for their support and agree that condition-specific episode measures address an area of need and will promote better care coordination.

After consideration of the public comments we received, we are finalizing a modification of our proposals for the episode-base payment measures. We are finalizing three of the four proposed measures (the Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure, the Cellulitis Clinical Episode-Based Payment measure, and the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure). We are not finalizing the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure.

In addition, we are postponing implementation and finalizing these three measures for the FY 2019 payment determination and subsequent years (CY 2017 performance period and subsequent years), instead of the FY 2018 payment determination and subsequent years (CY 2016 performance period and subsequent years) as proposed.

Furthermore, we will provide hospitals with confidential hospital-specific feedback reports containing performance data on these three measures during the interim FY 2018 payment determination (CY 2016 performance period) prior to inclusion for public reporting. Since we are not finalizing the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure, it will not be included in the confidential hospital-specific feedback reports.

c. Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

(1) Background

Between 2009 and 2012, there were 337,419 total hip arthroplasty (THA) procedures and 750,569 total knee arthroplasty (TKA) procedures for Medicare FFS patients 65 years and older.[168] More than one-third of the US population 65 years and older suffers from osteoarthritis,[169] a disabling condition for which elective THA/TKAs are most commonly performed. Estimates place the annual insurer cost of osteoarthritis in the United States at $149 billion, with Medicare payments to hospitals for THA/TKA exceeding $15 billion annually.[170]

There is evidence of variation in payments at hospitals for patients undergoing THA and/or TKA. The mean 90-day risk-standardized payment among Medicare FFS patients aged 65 or older with a qualifying elective primary THA/TKA procedure in 2010–2012 was $23,248, and ranged from $16,421 to $35,123 across 2,614 hospitals.[171] However, high or low payments to hospitals are difficult to interpret in isolation. Some high payment hospitals may have better clinical outcomes when compared with low payment hospitals while other high payment hospitals may not have better outcomes. Thus, CMS believes that this payment measure will provide complementary information to other THA/TKA quality measures in the Hospital IQR Program.

Quality measures for THA/TKA, such as: (1) Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) (77 FR 53515 through 53518), and (2) Hospital-level risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (77 FR 53519 through 53521), are already adopted in the Hospital IQR Program and publicly reported, making THA/TKA an ideal procedure for which to assess payments for Medicare patients and relative hospital value. Including this proposed measure in the Hospital IQR Program and publicly reporting it on *Hospital Compare* would provide stakeholders with additional information about a hospital's cost of care for THA/TKA that will complement information about a hospital's quality of care. By including payments for 90 days after admission, this hospital-level resource use measure can capture the full spectrum of care and encourage collaboration and shared responsibility for patients' health after their procedures.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24572 through 24574), we proposed to include this non-NQF-endorsed measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this final rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been endorsed by the NQF, and were unable to identify any measures that assess hospital risk-standardized payment associated with a 90-day episode-of-care for elective primary THA/TKA. We also are not aware of any other 90-day episode-of-care THA/TKA measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

The MAP conditionally supported this measure on December 10, 2014 pending a timely review by the NQF Cost and Resource Use Standing Committee. The MAP recommended

[168] Suter L, Grady JL, Lin Z *et al.*: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[169] Osteoarthritis. 2011; *http://www.cdc.gov/arthritis/basics/osteoarthritis.html.*

[170] Miller DC, Gust C, Dimick JB, Birkmeyer N, Skinner J, Birkmeyer JD.: Large variations in Medicare payments for surgery highlight savings potential from bundled payment programs. *Health Aff (Millwood).* Nov 2011;30(11):2107–2115.

[171] Kim N, Ott LS, Lin Z *et al.*: Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0). 2014. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

harmonizing and determining the most parsimonious approach to measuring the costs of hip and knee replacements to minimize the burden and confusion of competing methodologies.[172] Once the call for measures for the Cost and Resource Use project at NQF is announced, we will submit this measure for endorsement. In the meantime, we will consider ways to take these MAP recommendations into account.

(2) Overview of Measure and Rationale for Examining Payments for a 90-Day Episode-of-Care

The THA/TKA payment measure assesses hospital risk-standardized payment associated with a 90-day episode-of-care for elective primary THA/TKA for any hospital participating in the Hospital IQR Program.

When considering payments for Medicare patients, we focused on a 90-day episode-of-care triggered by admission for several key reasons. First, THA and TKA procedures require ongoing post-discharge care. Second, the 90-day preset window encourages hospitals to optimize post-discharge care. Third, mechanical complications and wound or joint infections may present after 30 days and rates of these complications remain elevated for at least 90 days. Fourth, the 90-day post-admission timeframe is consistent with CMS' THA/TKA complication measure, which captures specific complications up to 90 days after admission. Furthermore, we obtained input from a national Technical Expert Panel (TEP) on the most appropriate window for the episode-of-care. Based on TEP feedback, we chose a measure follow-up period of 90 days that includes all payments for the initial 30 days of the episode, and all payments in a predefined set of care settings and services for days 31 through 90.

We refer readers to the measure methodology report and measure risk adjustment statistical model on our Measure Methodology page, under the ''Downloads'' section of the Web page. We refer readers to the ''Hip and Knee Arthroplasty Payment'' zip file on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[172] National Quality Forum. The report is available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx* and the ''Spreadsheet of MAP 2015 Final Recommendations'' is available at: *http://www.qualityforum.org/map/*.

(3) Data Sources

The proposed Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary THA and/or TKA measure uses Part A and Part B Medicare administrative claims data that contain payments for Medicare FFS beneficiaries who were hospitalized and underwent an elective THA/TKA. This measure will use 3 years of data.

(4) Outcome

The primary outcome of this measure is the hospital-level risk-standardized payment for an elective primary THA/TKA episode-of-care. This measure captures payments for Medicare patients across multiple care settings, services, and supplies (inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, and durable medical equipment, prosthetics/orthotics, and supplies). This measure includes patient copayments as well as payments from coinsurance. While the approach to standardization in calculating payments over the episode is very similar to the previously adopted Hospital IQR Program measure, Payment-Standardized Medicare Spending Per Beneficiary (MSPB) as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626), the THA/TKA measure has a different cohort and risk-model. For more information on how MSPB is calculated, we refer readers to the measure development reports found on the QualityNet Web site at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350*.

To isolate payment variation that reflects practice patterns rather than CMS payment adjustments, this measure excludes policy and geography payment adjustments unrelated to clinical care decisions. We achieve this by ''stripping'' or ''standardizing'' payments for each care setting. Stripping refers to removing geographic differences and policy adjustments in payment rates for individual services from the total payment for that service. Standardizing refers to averaging payments across geographic areas for those services where geographic differences in payment cannot be stripped. Stripping and standardizing the payment amounts allows for a fair comparison across hospitals based solely on payments for decisions related to clinical care of THA/TKA.

By risk standardizing the payment measure, we are able to adjust for case-mix at any given hospital and compare a specific hospital's risk-standardized payment (RSP) to an average hospital with a similar case-mix. We define our analytic timeframe as beginning with the index admission for an elective primary THA/TKA to 90 days post-admission. The measurement includes all payments for the first 30 days after admission and only certain payments based on a pre-defined set of care settings and services for days 31–90.

(5) Cohort

The measure includes Medicare FFS patients aged 65 or older admitted for elective primary THA and/or TKA, and calculates payments made on behalf of these patients (including payments made by CMS, patients, and other insurers) over a 90-day episode-of-care beginning with the index admission. The measure cohort aligns with another previously adopted Hospital IQR Program measure—90-day hospital-level risk-standardized complication rate (RSCR) following elective primary THA and/or TKA (NQF #1550) (77 FR 53516 through 53518). Consistent with this previously adopted measure, the proposed measure includes hospitalizations identified by a procedure code of either THA or TKA, as classified by the ICD–9–CM codes 81.51 and 81.54, respectively. The measure includes only those hospitalizations from short-stay acute care hospitals in the index cohort and restricts the cohort to patients enrolled in FFS Medicare Parts A and B (with no Medicare Advantage coverage).

(6) Inclusion and Exclusion Criteria

This proposed measure includes hospitalizations for patients 65 years and older at the time of index admission. An index admission/hospitalization is the initial admission for a qualifying elective primary THA/TKA that triggers the 90-day episode-of-care for this payment measure. An index admission is the hospitalization to which the RSP outcome is attributed and includes index admissions for patients having a qualifying elective primary THA/TKA procedure. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients without at least 90 days of post-admission enrollment in FFS Medicare Parts A and B because this is necessary to identify the outcome (payments) in the dataset over the analytic period; (2) admissions for patients discharged against medical advice (AMA) because hospitals had limited opportunity to implement high quality care; (3) admissions for patients transferred to federal hospitals because we do not have claims data for these

hospitals, so including these patients would cause payments to be underestimated; (4) admissions for patients with more than two THA/TKA procedure codes during the index hospitalization because, although clinically possible, it is highly unlikely that patients would receive more than two elective THA/TKA procedures in one hospitalization, and this may reflect a coding error; (5) admissions that could not be matched to admissions in the THA/TKA complication measure because, as part of our data processing, we matched our index THA/TKA admissions to the THA/TKA complication measure cohort to obtain the risk-adjustment variables; and (6) admissions without a DRG weight and the provider received no payment because, without either DRG weight or payment data, we cannot calculate a payment for the patient's index admission.

(7) Risk Adjustment

The measure adjusts for differences across hospitals in how payments are affected by patient comorbidities relative to patients cared for by other hospitals. We refer readers to the measure risk adjustment statistical model on our Measure Methodology Web page, under the ''Downloads'' section of the Web page. Please see the ''Hip and Knee Arthroplasty Payment'' zip file on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(8) Calculating the Risk-Standardized Payment (RSP)

The measure is calculated using a hierarchical generalized linear model with a log link and an inverse Gaussian distribution, which is a widely accepted statistical method that enables fair evaluation of relative hospital performance by taking into account patient risk factors as well as the number of patients that a hospital treats. This statistical model accounts for the structure of the data (patients clustered within hospitals) and calculates: (1) How much variation in hospital payment overall is accounted for by patients' individual risk factors (such as age and other medical conditions); and (2) how much variation is accounted for by hospital-specific performance. This approach appropriately models a positive, continuous, right-skewed outcome like payment and also accounts for the types of patients a hospital treats (that is, hospital case mix), the number of patients it treats, and the quality of care it provides. This hierarchical generalized linear model is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals and sample sizes vary across hospitals. Clustered patients are within the same hospital, and the quality of care of the hospital affects all patients, so the outcomes for each hospital's patients are not fully independent (that is, completely unrelated) as is assumed by many statistical models. As noted above, the measure methodology defines hospital case mix based on the clinical diagnoses provided in the hospital claims for their patients' inpatient and outpatient visits for the 12 months prior to the THA/TKA hospitalization as well as select conditions indicated by secondary diagnosis codes on index admission. This methodology specifically does not, however, account for diagnoses present in the index admission that may indicate complications of care rather than patient comorbidities.

The RSP is calculated as the ratio of predicted payments to expected payments and then the ratio is multiplied by the national unadjusted average payment for an episode-of-care. The ratio is greater than one for hospitals that have higher payments than would be expected for an average hospital with similar cases and less than one if the hospital has lower payments than would be expected for an average hospital with similar cases. This approach is analogous to a ratio of ''observed'' or ''crude'' rate to an ''expected'' or ''risk-adjusted'' rate used in other similar types of statistical analyses. The RSP is a point estimate—the best estimate of a hospital's payment based on the hospital's case-mix.

To calculate the measure result for the Hospital IQR Program, we computed an interval estimate, which is similar to the concept of a confidence interval, to characterize the level of uncertainty around the point estimate. We use the point estimate and interval estimate to determine hospital performance (for example, higher than expected, as expected, or lower than expected). The interval estimate indicates that the true value of the payment ratio lies between the lower limit and the upper limit of the interval. For more detailed information on the calculation methodology, we refer readers to our Measure Methodology Web page, under the ''Downloads'' section. We refer readers to the ''Hip and Knee Arthroplasty Payment'' zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

We invited public comment on our proposal to adopt the Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary THA and/or TKA measure for the FY 2018 payment determination and subsequent years.

Comment: One commenter noted its appreciation that the proposed measure has a corresponding quality measure (THA/TKA Complications) in the Hospital IQR Program unlike previously developed episode-of-care payment measures and noted that this could help mitigate the potential for cost to be prioritized over quality improvements.

Response: We thank this commenter for its support of this measure and the corresponding THA/TKA complications measure. We note that we have developed three other episode-of-care payment measures for acute myocardial infarction (AMI), heart failure (HF), and pneumonia (PN), all of which also have a corresponding condition-specific mortality measure.

The THA/TKA episode-of-care payment measure's results are intended to reflect differences in payments for patients over a 90-day period that are influenced by hospital care decisions. However, these results alone do not reflect the quality of care provided by hospitals. The payment measure's results are more meaningful when presented in the context of other outcome measures to facilitate profiling hospital value (payments and quality). Accordingly, we aligned key specifications of the payment measure with those of the corresponding complication measure. We plan to report the results of the payment measure on *Hospital Compare* along with its corresponding complication measure results.

Comment: One commenter noted its appreciation that the proposed measure is limited to elective procedures.

Response: We appreciate this commenter's support for measurement of elective total hip and knee arthroplasty procedures.

Comment: Several commenters noted that they will not support the proposed measure until it is NQF-endorsed; but that they would support the measure once it receives NQF endorsement. One commenter recommended that this measure may be appropriate for a robust trial period to inform the NQF's decision to endorse the measure.

Response: We proposed to include this non-NQF-endorsed measure under the Hospital IQR Program exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act. This

provision provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We considered available measures that have been endorsed or adopted by the NQF. We also are not aware of any other similar measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic. We believe it is imperative to adopt this measure as it aims to address common elective procedures among Medicare beneficiaries with substantial variability in payments due to different practice patterns. In addition, the measure aligns with our priority objectives and the National Quality Strategy to transform the national healthcare system by measuring and rewarding affordable, quality care. This measure provides transparency on the payments made for Medicare beneficiaries undergoing THA/TKA. Hospitals receive detailed information on how they compare with other institutions regarding the amount and venues of resources expended on patients. Therefore, the measure provides insight to hospitals that is not otherwise possible. Given that hospitals have experience with similar payment measure methodology, such as the measures of AMI, HF and PN payment that are reported on *Hospital Compare,* we do not believe a trial period is warranted.

The MAP conditionally supported this measure on December 10, 2014 pending a timely review by the NQF Cost and Resource Use Standing Committee. Although the measure is not currently NQF-endorsed, it is pending submission to NQF for initial endorsement and will be brought to the entity once an appropriate project is called.

Comment: Several commenters supported the efforts of CMS to assess quality of care being delivered to THA/TKA patients. One commenter endorsed initiatives to encourage both high-quality THA/TKA care and collaboration among providers to promote efficiencies, and expressed that the THA/TKA episode-of-care payment measure may promote efficient patient care management.

Response: We thank commenters for their support of the THA/TKA episode-of-care payment measure methodology and inclusion in the Hospital IQR Program. Further, we thank the commenters for their support of our initiative to assess the quality of care delivered to THA/TKA patients.

Comment: Some commenters questioned the reliability, validity and feasibility of the measure. Specifically, the commenters questioned the validity of the THA/TKA payment measure, and expressed that there are concerns within the provider community about the validity of the payment determination model. The commenters highlighted concerns with the breadth of costs incorporated into the measure.

Response: We thank the commenters for their input. We developed this measure in consultation with national guidelines for publicly reported outcome measures, outside experts, and the public; we believe that the measure meets all validity, reliability, and feasibility requirements.

We ensure the measure reliability, in part, because this measure uses variables from claims data submitted by hospitals for payment, data from Medicare fee schedules, data from final rules for Medicare prospective payment systems and payment policies, and CMS-published wage index data. Our final rules dictate payment adjustments and fees for services for each year across care settings. By incorporating these publicly available final rules into our payment calculation, we ensure our payment calculations are reliably estimated for that year. In constructing the measure, we aimed to utilize only those data elements from the claims data that have both face validity and reliability. Moreover, we assess the measure reliability as part of the development process and found very strong reliability for this measure when comparing the results for hospitals measured with two different random samples.

In addition, during development of the THA/TKA payment measure, we convened a national TEP. We reviewed the cohort, outcome and risk-adjustment approach with the TEP as well as public comments on the measure. We asked the TEP to evaluate the face validity of the measure and the consensus of the TEP favored the face validity of the measure. Finally, the measure is consistent with the technical approach to outcomes measurement set forth in NQF guidance for outcomes measures,[173] CMS Measure Management System (MMS) guidance,[174] and the guidance articulated in the American Heart Association scientific statement, ''Standards for Statistical Models Used for Public Reporting of Health Outcomes.'' [175] Regarding the validity of the payment determination model, please note that we applied the same approach to determining payments for THA/TKA payment measure as was used in the NQF-endorsed episode-of-care payment measures for acute myocardial infarction, heart failure, and pneumonia. The payment outcome is determined by using CMS claims and for actual payments which are then adjusted to identify comparable resource utilization (for example, stripping out wage adjustments), this is consistent with the manner that payments are determined for other CMS measures such as the Medicare Spending per Beneficiary measure.

Regarding the breadth of costs assessed in the THA/TKA payment measure, we believe this measure gives stakeholders the opportunity to gain insight into a cascade of medical events triggered by THA/TKA hospitalization and the payments associated with those events. The measure sums payments for Medicare patients, including index admission as well as post-discharge payments for: readmission or other post-discharge inpatient care, skilled nursing facilities, outpatient providers, home health agencies, hospice care, physician/clinical laboratory/ambulance services, and durable medical equipment, prosthetics/orthotics, and supplies. From days 0–30, the measure includes all payments for claims made in this time period. From days 31–90, the measure includes only payments related to THA/TKA. The results show differences in the patterns of post-discharge care and associated payments for Medicare patients across a continuum of care beginning with a hospitalization for THA/TKA and following patients 90 days after admission. It is important to include this span of payment information to appropriately examine the patterns of post-discharge care. For full details, we

[173] Measure Evaluation Criteria. 2011; *http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx.* Accessed September 26, 2012.

[174] Measures Management System Overview. 2012; *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/index.html?redirect=/MMS/19_MeasuresManagementSystemBlueprint.asp.* Accessed September 27, 2012.

[175] Krumholz H, Brindis R, Brush J, *et al.* Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation. *Circulation.* Jan 24 2006;113(3):456–462.

refer readers to the Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0) 2014 Measure Methodology Report located in the Hip and Knee Arthroplasty Payment zip file (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*).

Comment: Some commenters expressed support for aspects of the THA/TKA payment measure specifications but recommended refinements to the proposed measure's risk-adjustment model. Specifically, the commenters noted the measure should be refined to risk adjust for prior use of health services, admissions sources, and administrative data on support systems and demographic data. Another commenter raised concerns with the measure's clinical risk adjustment specific to the scope and adequacy of the clinical risk adjustments variables.

Response: We appreciate the commenters' support and suggestions to consider prior use of health services, admission source, support systems, and demographic data in the THA/TKA payment measure risk-adjustment model. We note that the THA/TKA payment measure utilizes administrative claims data that do not include some of this information such as support systems (such as living with a spouse). Moreover, outcomes measures that are designed to highlight opportunities for more efficient care within a community generally do not include risk adjustment for factors such as the patient's admission source or prior use of health services because such factors may be the result of the patterns of care in the local health care system that the measure aims to illuminate. For instance, in a community with high rates of use of post-acute care services, more patients may come to the hospital from similar settings such as skilled nursing care in the pre-admission period. To incorporate prior use of skilled nursing care into the measures risk adjustment, could ''risk adjust'' away the high use of such services in the area in the measure. We note that the payment measure is intended to provide transparency into the variation of patterns of care that can be used to drive efficiency. Higher payments are not necessarily worse than lower payments.

We also note that the THA/TKA episode-of-care payment measure does include risk adjustment for 56 administrative claims-based variables to account for differences in patient case mix that could lead to differences in payments, including patient comorbidities. The measure includes risk variables that assess patient frailty, such as protein-calorie malnutrition, metastatic cancer, dementia, and age, and thus likely does capture the clinical risk factors most concerning to clinicians. In addition, the measure includes risk adjustment for demographic variables, including age and gender. For full details on the measure's clinical variables included in the risk adjustment, we refer readers to Table 5 of the Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0) 2014 Measure Methodology Report (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*).

Comment: Some commenters urged CMS to comply with the MAP's recommendation of harmonizing and determining the most parsimonious approach to measure the cost of hip and knee replacements. Furthermore, the commenters noted the need to minimize the burden and confusion of competing methodologies.

Response: While the ''MAP conditionally supported this measure pending a timely review of these measures by the NQF Cost and Resource Use Standing Committee to consider harmonization issues and determine the most parsimonious approach to measuring the costs of hip and knee replacements to minimize the burden and confusion of competing methodologies,'' [176] the Hospital IQR Program did not propose adopting other hip or knee replacement episode-of-care payment measures at this time. We do not agree that there are harmonization issues among competing measures for these procedures as it relates to this program. The measure approach is currently harmonized with the Hospital IQR Program AMI, HF, and PN payment measures that are publicly reported on *Hospital Compare.* As recommended by the MAP, we will work with NQF Cost and Resource Use Standing Committee to consider harmonization issues further when this measure is brought to NQF. In reference to the commenters' concerns about burden, this is a claims-based measure; therefore, since hospitals do not have to separately submit or report any additional data to CMS, there is no burden on hospitals for data collection or calculation of the THA/TKA payment measure.

Key specifications of the THA/TKA payment measure have been harmonized and are aligned with the corresponding THA/TKA complications measure methodology.

Comment: Several commenters opposed the measure, noting it is reflective of post-discharge costs as well as the actions of multiple health care entities, which are beyond the discharging hospital's control. The commenters stated that the measure is not actionable for hospitals, because the outcome includes costs that happen outside of the inpatient setting. One commenter further added that having a 90-day outcome timeframe is not reasonable as the hospital cannot affect Medicare program expenditures for this long period of time after the patient is discharged.

Response: We appreciate the commenters' views. When considering payments to hospitals, we attributed payments for an episode-of-care to the hospital since the episode is triggered by admission to an inpatient hospitalization. We focused on a 90-day episode-of-care for several key reasons. First, THA and TKA procedures require ongoing post-discharge care. Second, a fixed 90-day timeframe incentivizes hospitals to optimize post-discharge care. Third, mechanical complications and wound or joint infections may present after 30 days and rates of these complications remain elevated for at least 90 days. Fourth, the 90-day post-admission timeframe is consistent with CMS' THA/TKA complication measure, which captures specific complications up to 90 days after admission. Finally, a 90-day window was consistent with the timeframe recommended by members of our TEP.

The objective of this episode-of-care payment measure is to encourage efficiencies gained by well-coordinated care across a patient's experience of total hip/knee arthroplasty. Hospitalizations represent a brief period of care that requires ongoing management post-discharge and hospitals are often directly responsible for scheduling post-discharge follow-up. This measure includes only primary elective THA/TKA. Therefore, providers have an opportunity to plan for both the acute and post-acute care their patients will receive including follow-up visits, choice of rehabilitation facility or home health services, as well as necessary durable medical equipment. Hospital quality also influences the likelihood of costly prolonged hospital stay or returns to the hospital in the post-discharge

[176] ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/*.

period. Therefore, hospital care and decisions made at the admitting hospital affect not only the hospitalization payments, but also payments for care in the post-discharge period. We note that, to mitigate such concerns, only those payments that are considered directly related to the hip or knee replacement are included during the 31–90 day period. A full description of how related payments are determined can be found in the associated technical report at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

Comment: One commenter expressed concern about the accuracy of the administrative data sets used to develop the proposed measure.

Response: We thank the commenter for its concerns. For this measure, we have confidence in the ability to identify the cohort (patients with elective hip or knee replacement) using claims data as this measure uses the same cohort as the THA/TKA complication measure. The outcome of this measure is an assessment of payments made over the episode-of-care, which claims data are ideally suited for assessing. Finally, we have demonstrated validity of claims-based measures for profiling hospitals' performance historically for a number of previously developed measures, including a medical record validation of the hospital-level risk-standardized complication rate (RSCR) following elective primary THA/TKA. Specifically, we have validated the adequacy of risk-adjustment of claims models by building comparable models using medical record data for risk adjustment for heart failure patients, AMI patients, PN patients, stroke patients and CABG patients. In all of these cases, when both models were applied to the same patient population, the hospital risk-standardized mortality and readmission rates estimated using the claims-based risk-adjustment models had a high level of agreement with the results based on the medical record model, thus supporting the use of the claims-based models for public reporting. In addition, we validated the THA/TKA complication measure outcome definition through a medical record review, which produced a 99 percent agreement between the current claims-based definition of complications and medical record data.[177]

[177] Grosso LM, Curtis JP, Lin Z, *et al.* Hospital-level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA): Measure Methodology Report. June 2012 2012.

Comment: Some commenters expressed concern that the proposed measure does not add value for Medicare beneficiaries, because it doesn't assess quality of care or give beneficiaries a sense of their own financial obligation. The commenters also noted that the proposed measure does not add utility to the THA/TKA readmission and complication measures. One commenter supported CMS providing the resource use data to hospitals, but using a mechanism other than the Hospital IQR Program.

Response: We disagree with commenters and believe that the THA/TKA episode-of-care payment measure adds value for Medicare beneficiaries and is appropriate for the Hospital IQR Program.

We believe that even though this measure does not only reflect beneficiaries' own financial obligation, it still provides valuable information. This measure provides transparency on the payments made for Medicare beneficiaries undergoing THA/TKA. The THA/TKA episode-of-care payment measure's results are intended to reflect differences in payments for patients over a 90-day period that are influenced by hospital care decisions. Consumers will be able to examine the payment measure results to determine if the payments for the 90 day episode-of-care following a hip or knee replacement at a given hospital are higher than would be expected at an average hospital. This measure includes payments made by Medicare, other insurers, as well as patients themselves. We believe this transparency will provide information about variation in costs of care for THA/TKA that can inform patient decisions for this primary, elective procedure.

Furthermore, we believe this measure will be beneficial to patients, and is more meaningful, when presented in the context of other outcome measures to facilitate profiling hospital value (payments and quality); and so its inclusion in the Hospital IQR Program is appropriate and beneficial. We aligned key specifications of the payment measure with those of the corresponding complication measure already adopted in the Hospital IQR Program. We plan to report the results of the payment measure on *Hospital Compare* along with its corresponding complication measure results, thus expanding the utility of the readmission and complication measures by providing insight on payment and quality concurrently.

Comment: One commenter supported the THA/TKA payment measure's 90-day outcome timeframe and stated that capturing and sharing data on the full spectrum of care after a surgical procedure will encourage collaboration and shared accountability across the spectrum of clinicians, institutions and providers that serve patients in these care settings and this should be the expectation.

Response: We appreciate the commenter's support for assessing a 90-day outcome timeframe for the THA/TKA payment measure and agree that the measure will encourage collaboration and shared accountability for Medicare fee-for-service beneficiaries across the continuum of care beginning with a hospitalization for THA/TKA and following patients 90 days after admission.

Comment: A few commenters expressed the importance of having supportive educational materials for hospitals to learn the THA/TKA payment measure specifications. The commenters explained that implementing the THA/TKA payment measure will require sharing of granular resource use data in a manner that enables hospitals to identify opportunities to optimize clinical pathways.

Response: We appreciate the commenter's recommendation to provide hospitals with robust education materials for the Hospital-Level, Risk-Standardized Payment Associated with the 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure. We are committed to supporting stakeholders in their understanding of the measure specifications and will provide hospitals with the appropriate supporting resources. We note the measure technical report is currently available to access, and we refer readers to: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

In addition, as already established in the Hospital IQR Program, hospitals have the opportunity to review its data before they are made public (79 FR 50203). During this preview period prior to public reporting, we will send hospitals hospital-specific reports (HSRs) that will provide patient-level data, as well as State and national results. This will give hospitals an opportunity to review granular resource use data for the THA/TKA payment measure.

Comment: One commenter stated that CMS should ensure there is consensus among stakeholders about the THA/TKA payment measure prior to the measure's finalization and adoption into the Hospital IQR Program.

Response: We appreciate the commenter's recommendation to ensure that stakeholders reach consensus on the THA/TKA payment measure prior to public reporting. As stated in previous rulemaking (74 FR 43861), we believe that consensus among affected parties also can be reflected by several means, including consensus achieved during the measure development process (which includes MAP input), consensus shown through broad acceptance and use of measures, via NQF endorsement, and consensus through public comment. This measure has been evaluated by a national TEP and has been subject to a public comment period held during the measure development period where stakeholders could comment on the technical specifications on the measure. Several commenters expressed strong support of the development of this measure and CMS' efforts to improve efficiency and incentivize high quality care for THA/TKA patients across a continuum of care. We did not make changes to the technical specifications of the measure due to comments received during the measure development public comment period, but we will take the comments into consideration during the annual measure reevaluation process.

The MAP conditionally supported this measure on December 10, 2014 pending a timely review by the NQF Cost and Resource Use Standing Committee. Although the measure is not currently NQF endorsed, it is pending submission to NQF for initial endorsement and will be brought to the entity once an appropriate project is called.

After consideration of the public comments we received, we are finalizing the Hospital Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary THA and/or TKA measure for the FY 2018 payment determination and subsequent years as proposed.

d. Excess Days in Acute Care After Hospitalization for Acute Myocardial Infarction

(1) Background

Acute myocardial infarction (AMI) is a priority area for outcomes measurement because it is a common condition associated with considerable morbidity, mortality, and healthcare spending. We note that AMI was the tenth most common principal discharge diagnosis among patients with Medicare in 2012.[178] AMI also accounts for a large fraction of hospitalization costs, and it was the sixth most expensive condition billed to Medicare in 2011.[179]

Some of the costs for AMI can be attributed to high acute care utilization for post-discharge AMI patients in the form of readmissions, observation stays, and ED visits. We note that patients admitted for AMI have disproportionately high readmission rates, and that readmission rates following discharge for AMI are highly variable across hospitals in the United States.[180] [181] For the previously adopted Hospital IQR Program measure, Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (CY 2009 OPPS/ASC final rule with comment period; 73 FR 68780 through 68781) (hereinafter referred to as READM–30–AMI), publicly reported 30-day risk-standardized readmission rates for AMI ranged from 17.5 percent to 30.3 percent for the time period between July 2011 and June 2012.[182] However, patients are not only at risk of requiring readmission in the post-discharge period. ED visits represent a significant proportion of post-discharge acute care utilization. Two recent studies conducted in patients of all ages have shown that 9.5 percent of patients return to the ED within 30 days of hospital discharge and that about 12 percent of these patients are discharged from the ED and are not captured by the previously adopted Hospital IQR Program READM–30–AMI measure.[183] [184]

In addition, over the past decade, the use of observation stays has rapidly increased. Specifically, between 2001 and 2008, the use of observation services increased nearly three-fold,[185] and significant variation has been demonstrated in the use of observation services for conditions such as chest pain.[186] These rising rates of observation stays among Medicare beneficiaries have gained the attention of patients, providers, and policymakers.[187] For example, a report from OIG noted that in 2012, Medicare beneficiaries had 1.5 million observation stays.[188] Many of these observation stays lasted longer than the intended one day. This OIG report also noted the potential relationship between hospital use of observation stays as an alternative to short-stay inpatient hospitalizations as a response to changing hospital payment incentives.[189]

Thus, in the context of the previously adopted and publicly reported READM–30–AMI measure, the increasing use of ED visits and observation stays has raised concerns that the READM–30–AMI measure does not capture the full range of unplanned acute care in the post-discharge period. In particular, there exists concern that high use of observation stays could in some cases replace readmissions, and hospitals with high rates of observation stays in the post-discharge period may therefore have low readmission rates that do not accurately reflect the quality of care.[190]

In response to these concerns, CMS improved on a previously existing non-Hospital IQR Program measure entitled ''30-Day Post-Hospital AMI Discharge Care Transition Composite'' (NQF

[178] Agency for Healthcare Research and Quality (AHRQ). *Healthcare Cost and Utilization Project (HCUP)* Available at: *http://hcupnet.ahrq.gov/.*

[179] Torio CM, Andrews RM.: National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. HCUP Statistical Brief #160. 2013; *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.jsp.*

[180] Krumholz HM, Merrill AR, Schone EM, *et al.*: Patterns of hospital performance in acute myocardial infarction and heart failure 30-day mortality and readmission. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2009;2(5):407–413.

[181] Bernheim SM, Grady JN, Lin Z, *et al.*: National patterns of risk-standardized mortality and readmission for acute myocardial infarction and heart failure. Update on publicly reported outcomes measures based on the 2010 release. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2010;3(5):459–467.

[182] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook Performance Report on Outcome Measures September 2013. September 2013; Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/-Medicare-Hospital-Quality-Chartbook-2013.pdf.*

[183] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

[184] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA: The journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[185] Venkatesh AK GB, Gibson Chambers JJ, Baugh CW, Bohan JS, Schuur JD.: Use of Observation Care in US Emergency Departments, 2001 to 2008. *PLoS One.* September 2011;6(9):e24326.

[186] Schuur JD, Baugh CW, Hess EP, Hilton JA, Pines JM, Asplin BR.: Critical pathways for post-emergency outpatient diagnosis and treatment: Tools to improve the value of emergency care. *Academic Emergency Medicine.* Jun 2011;18(6):e52–63.

[187] Feng Z, Wright B, Mor V.: Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. *Health Affairs.* Jun 2012;31(6):1251–1259.

[188] Wright S.: *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI–02–12–00040.* Washington, DC: Department of Health and Human Services: Office of Inspector General July 29, 2013.

[189] Wright S.: *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI–02–12–00040.* Washington, DC: Department of Health and Human Services: Office of Inspector General July 29, 2013.

[190] Carlson J.: Faulty Gauge? Readmissions are down, but observational-status patients are up and that could skew Medicare numbers. *Modern Healthcare.* June 8, 2013 2013.

#0698). The improved measure (now called Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction) is a risk-adjusted outcome measure for AMI that incorporates the full range of acute care use that patients may experience post-discharge: Hospital readmissions, observation stays, and ED visits.

The measure assesses all-cause acute care utilization for post-discharge AMI patients for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. It is costly, exposes patients to additional risks of medical care, interferes with work and family care, and imposes significant burden on caregivers. Second, limiting the measure to inpatient utilization may make it susceptible to gaming. Finally, it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit. Therefore, this measure includes all-cause utilization.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24574 through 24576), we proposed to include this improved measure under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this final rule. We considered existing measures related to care transitions that have been endorsed by the NQF. Existing process measures capture many important domains of care transitions such as education, medication reconciliation and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We also are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays, and ED visits) following hospitalization for AMI that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

The MAP conditionally supported this measure on the condition that this measure is reviewed by NQF and endorsed. We refer readers to the Spreadsheet of MAP 2015 Final Recommendations available at: *http://www.qualityforum.org/map/*, and note that in the document, this measure is entitled ''Hospital 30-day, all-cause, unplanned risk-standardized days in acute care following acute myocardial infarction (AMI) hospitalization.'' In particular, MAP members noted that the measure should be considered for SDS adjustment in the upcoming NQF trial period, reviewed for the empirical and conceptual relationship between SDS factors and risk-standardized days following acute care, and endorsed with appropriate consideration of SDS factors as determined by NQF standing committees. Some MAP members noted this measure could help address concerns about the growing use of observation stays. We note that this measure will be submitted to NQF with appropriate consideration for SDS, if required, for endorsement proceedings once an appropriate measure endorsement project has a call for measures.

(2) Overview of Measure

This Excess Days in Acute Care after Hospitalization for AMI measure is a risk-standardized outcome measure that compares the number of days that patients are predicted to spend in acute care across the full spectrum of possible acute care events (hospital readmissions, observation stays, and ED visits) after discharge from a hospital for AMI, compared to the days expected based on their degree of illness.

(3) Data Sources

The proposed measure is administrative claims-based and will use 3 years of data. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for AMI.

(4) Outcome

The outcome of the measure is the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. The measure defines days in acute care as days spent: (1) In an ED, (2) admitted to observation status, or (3) admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index AMI hospitalization. Readmission days are calculated as the discharge date minus the admission date. Admissions that extend beyond the 30-day follow-up period are truncated on day 30. Observation days are calculated by the hours in observation, rounded up to the nearest half day. On the advice of our TEP, an ED treat-and-release visit is counted as one half day. ED visits are not counted as a full day because the majority of treat-and-release visits last fewer than 12 hours.

''Planned'' readmissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. This measure excludes planned readmissions using the planned readmission algorithm previously developed for the READM–30–AMI measure. A more detailed discussion of exclusions follows below.

The measure counts all use of acute care occurring in the 30-day post-discharge period. For example, if a patient returns to the ED three times, the measure counts each ED visit as a half-day. Similarly, if a patient has two hospitalizations within 30 days, the days spent in each are counted. We take this approach to capture the full patient experience of need for acute care in the post-discharge period.

(5) Cohort

We defined the eligible cohort using the same criteria as the existing Hospital IQR Program measure, READM–30–AMI, except that this proposed measure does not include patients admitted to Veterans Administration hospitals. That is, the cohort includes Medicare FFS patients aged 65 years or older: (1) With a principal discharge diagnosis of AMI; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to another acute care facility; and (5) were alive at discharge. We defined the cohorts using the following ICD–9–CM diagnosis codes identified in inpatient claims data:

- 410.00 (Acute myocardial infarction of anterolateral wall, episode of care unspecified);
- 410.01 (Acute myocardial infarction of anterolateral wall, initial episode of care);
- 410.10 (Acute myocardial infarction of other anterior wall, episode of care unspecified);
- 410.11 (Acute myocardial infarction of other anterior wall, initial episode of care);
- 410.20 (Acute myocardial infarction of inferolateral wall, episode of care unspecified);
- 410.21 (Acute myocardial infarction of inferolateral wall, initial episode of care);
- 410.30 (Acute myocardial infarction of inferoposterior wall, episode of care unspecified);
- 410.31 (Acute myocardial infarction of inferoposterior wall, initial episode of care);
- 410.40 (Acute myocardial infarction of other inferior wall, episode of care unspecified);

- 410.41 (Acute myocardial infarction of other inferior wall, initial episode of care);
- 410.50 (Acute myocardial infarction of other lateral wall, episode of care unspecified);
- 410.51 (Acute myocardial infarction of other lateral wall, initial episode of care);
- 410.60 (True posterior wall infarction, episode of care unspecified);
- 410.61 (True posterior wall infarction, initial episode of care);
- 410.70 (Subendocardial infarction, episode of care unspecified);
- 410.71 (Subendocardial infarction, initial episode of care);
- 410.80 (Acute myocardial infarction of other specified sites, episode of care unspecified);
- 410.81 (Acute myocardial infarction of other specified sites, initial episode of care);
- 410.90 (Acute myocardial infarction of unspecified site, episode of care unspecified);
- 410.91 (Acute myocardial infarction of unspecified site, initial episode of care).

(6) Exclusion Criteria

The measure excludes the following admissions from the measure cohort: (1) Hospitalizations without at least 30 days of post-discharge enrollment in Part A and Part B FFS Medicare because the 30-day outcome cannot be assessed in this group since claims data are used to determine whether a patient was readmitted, was placed under observation, or visited the ED; (2) discharged against medical advice (AMA) because providers did not have the opportunity to deliver full care and prepare the patient for discharge; (3) hospitalizations for patients admitted and discharged on the same day (and not transferred or deceased) because these patients likely did not suffer clinically significant AMI; and (4) hospitalizations for patients with an index admission within 30 days of a previous index admission because additional AMI admissions within 30 days are part of the outcome, and we choose not to count a single admission both as an index admission and a readmission for another index admission.

(7) Risk-Adjustment

The measure adjusts for variables that are clinically relevant and have strong relationships with the outcome. The measure seeks to adjust for case-mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. The measure does not adjust for patients' admission source or their discharge disposition (for example, skilled nursing facility) because these factors are associated with the structure of the healthcare system, not solely patients' clinical comorbidities. Regional differences in the availability of post-acute care providers and practice patterns might exert undue influence on model results. In addition, these data fields are not audited and are not as reliable as diagnosis codes.

The outcome is risk adjusted using a two-part random effects model. This statistical model, often referred to as a ''hurdle'' model, accounts for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, it models the number of acute care days for each patient as: (a) A probability that they have a non-zero number of days; and (b) a number of days, given that this number is non-zero. The first part is specified as a logit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This is an accepted statistical method that explicitly estimates how much of the variation in acute care days is accounted for by patient risk factors, how much by the hospital where the patient is treated, and how much is explained by neither. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days for each patient, and the average difference between these for each hospital is used to construct the risk-standardized Excess Acute Care Days.

(8) Calculating Excess Acute Care Days (EACD)

The EACD is calculated as the difference between the average of the predicted number of days spent in acute care for patients discharged from each hospital and the average number of days that would have been expected if those patients had been cared for at an average hospital, and then the difference is multiplied by 100 so that EACD represents EACD per 100 discharges. We multiply the final measure by 100 to be consistent with the reporting of the existing READM–30–AMI measure. A positive result indicates that patients spend more days in acute care post-discharge than expected; a negative result indicates that patients spend fewer days in acute care than expected.

We invited public comment on our proposal to adopt the Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction measure for the FY 2018 payment determination and subsequent years.

Because comments received apply to both the Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction measure and Excess Days in Acute Care after Hospitalization for Heart Failure measure, we discuss comments and our final policies for both measures at the end of section VIII.A.7.e.(8) of the preamble of this final rule.

e. Excess Days in Acute Care After Hospitalization for Heart Failure

(1) Background

Heart failure is a priority area for outcomes measurement because it is a common condition associated with considerable morbidity, mortality, and healthcare spending. Heart failure was the second most common principal discharge diagnosis among patients with Medicare in 2012.[191] Heart failure also accounts for a large fraction of hospitalization costs, and it was the third most expensive condition billed to Medicare in 2011.[192]

Some of the costs for heart failure can be attributed to high acute care utilization for post-discharge heart failure patients in the form of readmissions, observation stays, and ED visits. Patients admitted for heart failure have disproportionately high readmission rates. Readmission rates following discharge for heart failure are highly variable across hospitals in the United States.[193] [194] For the previously adopted Hospital IQR Program measure, Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Heart Failure Hospitalization (NQF #0330) (READM–30–HF) (73 FR

[191] Agency for Healthcare Research and Quality (AHRQ). *Healthcare Cost and Utilization Project (HCUP)* Available at: *http://hcupnet.ahrq.gov/.*

[192] Torio CM, Andrews RM. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. HCUP Statistical Brief #160. 2013; Available at: *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.jsp.*

[193] Krumholz HM, Merrill AR, Schone EM, et al.: Patterns of hospital performance in acute myocardial infarction and heart failure 30-day mortality and readmission. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2009;2(5):407–413.

[194] Bernheim SM, Grady JN, Lin Z, et al.: National patterns of risk-standardized mortality and readmission for acute myocardial infarction and heart failure. Update on publicly reported outcomes measures based on the 2010 release. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2010;3(5):459–467.

46806 through 48610), publicly reported 30-day risk-standardized readmission rates for heart failure ranged from 17.5 percent to 30.3 percent for the time period between July 2011 and June 2012.[195] However, patients are not only at risk of requiring readmission in the post-discharge period. ED visits represent a significant proportion of post-discharge acute care utilization. Two recent studies conducted in patients of all ages have shown that 9.5 percent of patients return to the ED within 30 days of hospital discharge and that about 12 percent of these patients are discharged from the ED and are not captured by the previously adopted Hospital IQR Program READM–30–HF measure.[196] [197] Patients returning to the ED after heart failure hospitalization most commonly return for heart failure recurrence and chest pain.[198]

In addition, over the past decade, the use of observation stays has rapidly increased. Specifically, between 2001 and 2008, the use of observation services increased nearly three-fold,[199] and significant variation has been demonstrated in the use of observation services for conditions such as chest pain.[200] These rising rates of observation stays among Medicare beneficiaries have gained the attention of patients, providers, and policymakers.[201] [202] [203] For example, a report from the OIG noted that in 2012, Medicare beneficiaries had 1.5 million observation stays.[204] Many of these observation stays lasted longer than the intended one day. The OIG report also noted the potential relationship between hospital use of observation stays as an alternative to short-stay inpatient hospitalizations as a response to changing hospital payment incentives.

Thus, in the context of the currently adopted and publicly reported Hospital IQR Program READM–30–HF measure, the increasing use of ED visits and observation stays has raised concerns that the READM–30–HF measure does not capture the full range of unplanned acute care in the post-discharge period. In particular, there exists concern that high use of observation stays could in some cases replace readmissions, and hospitals with high rates of observation stays in the post-discharge period may therefore have low readmission rates that do not accurately reflect the quality of care.[205]

In response to these concerns, we improved on an existing non-Hospital IQR Program measure entitled ''30-Day Post-Hospital HF Discharge Care Transition Composite'' (NQF #0699). The improved measure (now called Excess Days in Acute Care after Hospitalization for Heart Failure) is a risk-adjusted outcome measure for heart failure that incorporates the full range of acute care use that patients may experience post-discharge: Hospital readmissions, observation stays, and ED visits.

The measure assesses all-cause acute care utilization for post-discharge heart failure patients for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. It is costly, exposes patients to additional risks of medical care, interferes with work and family care, and imposes significant burden on caregivers. Second, limiting the measure to inpatient utilization may make it susceptible to gaming. Finally, it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit. Therefore, this measure includes all-cause utilization.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24576 through 234779), we proposed this improved measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this final rule. We considered other existing measures related to care transitions that have been endorsed by the NQF. Existing process measures capture many important domains of care transitions such as education, medication reconciliation and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We also are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays and ED visits) following hospitalization for heart failure that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

The MAP conditionally supported this measure on the condition that it is reviewed by NQF and endorsed, as detailed in the ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/*. We note that this measure was entitled ''Hospital 30-day, all-cause, unplanned risk-standardized days in acute care following heart failure hospitalization,'' in the MAP Spreadsheet. In particular, MAP members noted that the measure should be considered for SDS adjustment in the upcoming NQF trial period, reviewed for the empirical and conceptual relationship between SDS factors and risk-standardized days following acute care, and endorsed with appropriate consideration of SDS factors as determined by NQF standing committees. Some MAP members noted this measure could help address concerns about the growing use of observation stays. We note that this measure will be submitted to NQF with appropriate consideration for SDS, if required, for endorsement proceedings once an appropriate measure endorsement project has a call for measures.

(2) Overview of Measure

This Excess Days in Acute Care after Hospitalization for Heart Failure measure is a risk-standardized outcome measure that compares the number of days that patients are predicted to spend in acute care across the full spectrum of possible acute care events (hospital

[195] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook Performance Report on Outcome Measures September 2013. September 2013; Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/-Medicare-Hospital-Quality-Chartbook-2013.pdf*.

[196] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

[197] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA: The journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[198] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA: The journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[199] Venkatesh AK GB, Gibson Chambers JJ, Baugh CW, Bohan JS, Schuur JD.: Use of Observation Care in US Emergency Departments, 2001 to 2008. *PLoS One.* September 2011;6(9):e24326.

[200] Schuur JD, Baugh CW, Hess EP, Hilton JA, Pines JM, Asplin BR.: Critical pathways for post-emergency outpatient diagnosis and treatment: Tools to improve the value of emergency care. *Academic Emergency Medicine.* Jun 2011;18(6):e52–63.

[201] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

[202] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA: The journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[203] Feng Z, Wright B, Mor V.: Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. *Health Affairs.* Jun 2012;31(6):1251–1259.

[204] Wright S.: *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI–02–12–00040.* Washington, DC: Department of Health and Human Services: Office of Inspector General July 29, 2013.

[205] Carlson J.: Faulty Gauge? Readmissions are down, but observational-status patients are up and that could skew Medicare numbers. *Modern Healthcare.* June 8, 2013 2013.

readmissions, observation stays, and ED visits) after discharge from a hospital for heart failure, compared to the days expected at an average hospital, based on their degree of illness.

(3) Data Sources

The proposed measure is administrative claims-based and will use 3 years of data. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for heart failure.

(4) Outcome

The outcome of the measure is the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. The measure defines days in acute care as days spent: (1) In an ED; (2) admitted to observation status; or (3) admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index heart failure hospitalization. Readmission days are calculated as the discharge date minus the admission date. Admissions that extend beyond the 30-day follow-up period are truncated on day 30. Observation days are calculated by the hours in observation, rounded up to the nearest half day. On the advice of our TEP, an ED treat-and-release visit is counted as one half day. ED visits are not counted as a full day because the majority of treat-and-release visits last fewer than 12 hours.

''Planned'' readmissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. This measure excludes planned readmissions using the planned readmission algorithm (78 FR 50786 through 50787), a set of criteria for classifying readmissions that are likely to be planned among the general Medicare population using Medicare claims data, previously developed for Hospital IQR Program 30-day readmission measures, including the previously adopted READM–30–HF measure.

The measure counts all use of acute care occurring in the 30-day post-discharge period. For example, if a patient returns to the ED three times, the measure counts each ED visit as a half-day. Similarly, if a patient has two hospitalizations within 30 days, the days spent in each are counted. We take this approach to capture the full patient experience of need for acute care in the post-discharge period.

(5) Cohort

We defined the eligible cohort using the same criteria as the previously adopted Hospital IQR Program READM–30–HF measure (73 FR 46806 through 48610). The READM–30–HF cohort criteria are included in a report posted on our Measure Methodology Web page, under the ''Downloads'' section in the ''AMI, HF, PN, COPD, and Stroke Readmission Updates'' zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. This measure differs from the READM–30–HF measure cohort in that this measure does not include patients admitted to Veterans Administration hospitals. That is, the cohort includes Medicare FFS patients aged 65 years or older: (1) With a principal discharge diagnosis of heart failure; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to another acute care facility; and (5) were alive at discharge. We defined the cohorts using the following ICD–9–CM diagnosis codes identified in inpatient claims data:

- 402.01 (Malignant hypertensive heart disease with heart failure);
- 402.11 (Benign hypertensive heart disease with heart failure);
- 402.91 (Unspecified hypertensive heart disease with heart failure);
- 404.01 (Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified);
- 404.03 (Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease);
- 04.11 (Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified);
- 404.13 (Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease);
- 404.91 (Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified);
- 404.93 (Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease);
- 428.0 (Congestive heart failure, unspecified);
- 428.1 (Left heart failure);
- 428.20 (Systolic heart failure, unspecified);
- 428.21 (Acute systolic heart failure);
- 428.22 (Chronic systolic heart failure);
- 428.23 (Acute on chronic systolic heart failure);
- 428.30 (Diastolic heart failure, unspecified);
- 428.31 (Acute diastolic heart failure);
- 428.32 (Chronic diastolic heart failure);
- 428.33 (Acute on chronic diastolic heart failure)
- 428.40 (Combined systolic and diastolic heart failure, unspecified);
- 428.41 (Acute combined systolic and diastolic heart failure);
- 428.42 (Chronic combined systolic and diastolic heart failure);
- 428.43 (Acute on chronic combined systolic and diastolic heart failure);
- 428.9 (Heart failure, unspecified).

(6) Exclusion Criteria

The measure excludes the following admissions from the measure cohort: (1) Hospitalizations without at least 30 days of post-discharge enrollment in Part A and Part B FFS Medicare because the 30-day outcome cannot be assessed in this group because claims data are used to determine whether a patient was readmitted, was placed under observation, or visited the ED; (2) discharged against medical advice (AMA) because providers did not have the opportunity to deliver full care and prepare the patient for discharge; and (3) hospitalizations for patients with an index admission within 30 days of a previous index admission because additional heart failure admissions within 30 days are part of the outcome, and we choose not to count a single admission both as an index admission and a readmission for another index admission.

(7) Risk-Adjustment

The measure adjusts for variables that are clinically relevant and have strong relationships with the outcome. The measure seeks to adjust for case-mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. The measure does not adjust for patients' admission source or their discharge

disposition (for example, skilled nursing facility) because these factors are associated with the structure of the health care system, not solely patients' clinical comorbidities. Regional differences in the availability of post-acute care providers and practice patterns might exert undue influence on model results. In addition, these data fields are not audited and are not as reliable as diagnosis codes.

The outcome is risk adjusted using a two-part random effects model. This statistical model, often referred to as a ''hurdle'' model, accounts for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, it models the number of acute care days for each patient as: (a) A probability that they have a non-zero number of days and (b) a number of days, given that this number is non-zero. The first part is specified as a logit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This is an accepted statistical method that explicitly estimates how much of the variation in acute care days is accounted for by patient risk factors, how much by the hospital where the patient is treated, and how much is explained by neither. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days for each patient, and the average difference between these for each hospital is used to construct the risk-standardized Excess Acute Care Days.

(8) Calculating Excess Acute Care Days (EACD)

The EACD is calculated as the difference between the average of the predicted number of days spent in acute care for patients discharged from each hospital and the average number of days that would have been expected if those patients had been cared for at an average hospital, and then the difference is multiplied by 100 so that EACD represents EACD per 100 discharges. We multiply the final measure by 100 to be consistent with the reporting of the existing READM–30–HF measure. A positive result indicates that patients spend more days in acute care post-discharge than expected; a negative result indicates that patients spend fewer days in acute care than expected.

We invited public comment on our proposals to adopt both the Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure measure and the Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction measure (hereinafter, collectively referred to as the EDAC measures) for the FY 2018 payment determination and subsequent years.

Comment: One commenter supported the EDAC measures. The commenter believed that for some conditions, like AMI and HF, the increase in ED visits and observations stays raises the concern that readmission measures are not fully capturing the range of unplanned care post-discharge. The commenter noted that an all-cause acute care utilization measure is beneficial to patients as any cause for acute care is undesirable and exposure to medical care has risks. The commenter believed that the proposed measures also address the unintended consequence of shifting patients outside of inpatient care.

Response: We thank the commenter for its support.

Comment: Several commenters opposed the proposed addition of the EDAC measures, noting that the measures include a cohort of patients with multiple risk levels. The commenters also noted that the measures do not make adjustments for mortality and suggest that risks of death be included in this measure. Finally, the commenters expressed their concerns that large academic medical centers will be penalized because of the generally underserved populations that they serve and therefore, believed that there was a greater need for specific risk adjustment factors.

Response: We appreciate the commenters' concern that the measures include patients with a wide range of severity or multiple risk levels. The EDAC measures' cohorts were reviewed by clinical experts and a TEP and were subject to a separate public comment period prior to the proposed rule. Stakeholders agreed with harmonizing the cohorts and risk-adjustment models of the EDAC measures with those of the readmission measures for heart failure and AMI. As a result, we believe these are clinically coherent cohorts.

Although the cohorts may contain patients with different disease severity, and therefore, different levels of risk, these measures are risk-adjusted to account for the fact that hospitals may have a different mix of patients with differing disease severity. For more details about the risk-adjustment methodology, we refer readers to the measures' methodology reports on our Measure Methodology Web page, under the ''Downloads'' section of the Web page. Please see the ''AMI Excess Days in Acute Care'' and ''HF Excess Days in Acute Care'' zip files on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. However, we will continue to monitor how hospital performance may be influenced by hospital type.

Regarding adjusting for mortality, although death is not included as an outcome in the EDAC measures, the risk of death is accounted for within the EDAC measures. The EDAC measures only assess whether patients return to acute care during post-discharge days in which a patient is alive and therefore, at risk of returning to acute care in the ''denominator.'' Because some patients do not survive 30 days, not all patients are at the same risk for an acute event for the same amount of time. Therefore, we calculated exposure time as the number of days each patient survives after discharge, which is incorporated as part of the outcome. Moreover, to ensure that mortality rates are considered, we also report separate measures of 30-day mortality for AMI and heart failure within the Hospital IQR Program.

Comment: One commenter asked for definitions of various ''Discharge Disposition'' designations, including Group Home (and how it differs from Disposition Home) and Assisted Living Facility. In addition, the commenter requested additional information on the definition of a State-designated Assisted Living Facility and how to determine if a facility is a disposition home or an intermediate care facility. Finally, the commenter requested clarification on which discharge disposition is to be used when a patient leaves against medical advice and either goes to another acute care hospital on the same day, in a few days, or it is unknown where the patient goes.

Response: The EDAC measures only use discharge disposition to identify patients who die during their hospitalization, or leave against medical advice. Patients whose discharge dispositions indicate that they left against medical advice are not included in them measure regardless of whether they go to another acute care hospital on the same day, in a few days, or it is unknown where the patient goes. Discharge disposition codes are not used to identify any other cases for exclusion from the measures or in the risk adjustment. We do not examine discharge disposition in the group home, assisted living facility, and intermediate care facility settings for this measure. We only examine returns to acute care settings and short-term acute care hospitals as well as if there are observation stays and emergency room visits.

Comment: Some commenters expressed concern that the measures may result in unintended consequences, including incentivizing hospitals to transition patients too quickly. Another commenter expressed concern that the proposed measures could create an incentive for hospitals to withhold specific types of medications that reduce mortality and hospitalization in the long term but may destabilize and necessitate more urgent care for patients in the short-term.

Response: We appreciate the concern about potential unintended consequences of the EDAC measures. Although we believe it is unlikely that hospitals would be motivated by the measures to transition patients having higher-risk HF or AMI diagnoses too quickly, we will consider ways to monitor for shifts in their care. We also believe it is unlikely that hospitals would withhold necessary medications from their patients as a result of publicly reporting these measures. We recognize that some hospital returns are unavoidable. However, others may result from poor quality of care, overutilization of care or inadequate transitional care. Improving the number of excess days in acute care is the joint responsibility of hospitals and other clinicians. Actions taken by hospital staff while preparing to transition the patient to outpatient status can minimize a patient's risk for adverse outcomes, as can collaboration and communication between the inpatient and outpatient providers within a community. Measuring excess days in acute care will support existing incentives to invest in interventions to improve hospital care, better assess the readiness of patients for discharge, and facilitate transitions to outpatient status.

Comment: A few commenters opposed the proposal to adopt the EDAC measures because they believe that hospitals are already penalized for extended stays through the cap on payments regardless of Length of Stay (LOS). The commenters also noted that there are external factors that influence length of stay, including issues placing patients, restrictions on ordering respiratory services, and appeals on discharge plans. One commenter stated that it did not believe that LOS is a valid proxy for resource use.

Response: The EDAC measures are not intended to penalize hospitals for extended stays and we recognize that some factors are partially outside of a hospital's control, such as delays in placement as noted by the commenter. These measures are intended to help patients and providers understand variation among hospitals in the days that are spent by patients in acute care settings following a discharge for AMI and HF. The measures provide a broader perspective on post-discharge events than the current readmission measures and are intended to incentivize improvements in care transitions from the hospital so that patients are less likely to return to the acute setting. The measures examine both the utilization of services (that is, whether or not a patient returned to the hospital for an ED visit, observation stay, or readmission) as well as the amount of time in those acute care settings in the 30-day period following discharge from the hospital.

The measures are not intended as resource use measures, but do count the days in acute care. This reason for the use of a day count is two-fold: Longer stays may reflect that patients are returning with greater severity of illness and also because it reflects the experience of patients; the longer the stay, the greater the direct impact on the patients in terms of lost days of work or caregiving, cost, and risk of complications.

Comment: A few commenters noted that these episodes each reflect different approaches to patient-centered care and should not be combined into a single number, especially because the ''2-midnight'' policy and MSBP measure already monitor these indicators. The commenters expressed serious reservations regarding the EDAC measures. One commenter believed that the proposed excess days measures would add to an existing overlap where hospitals are already penalized for excess readmissions and all of the costs that would be included in the new EDAC measures would already be captured by the Medicare Spending per Beneficiary (MSPB) measure.

Several commenters were concerned that the inclusion of observation patients in the new excess acute care day measures masks the root causes of the increased use of observation stays which the commenter contended is the Recovery Audit Contractor process and the ''2-midnight'' policy. For this reason, the commenters encouraged CMS to further refine the RAC program as well as refine the assignment of patient status to ensure readmission measurement accuracy.

Response: The ''2-midnight'' policy provides guidance as to when an inpatient admission is appropriate for payment under Medicare Part A, but does not help beneficiaries to select providers or understand post-discharge acute care use. Although the MSPB measure may capture similar events, it provides a very different perspective based on the Medicare payments for such events. MSPB is focused on Medicare payments whereas the proposed EDAC measures are focused on excess days. The EDAC measures are intended to provide patients and providers a perspective on variation among hospitals in the number of days spent in acute care during the 30-day post-discharge period as compared to what would be expected at an average hospital. The EDAC measures capture a range of post-discharge outcomes that are important to patients.

The EDAC measures are not being finalized for use in a pay-for-performance program, only for use in the pay-for-reporting Hospital IQR Program. Although these measures and the readmission measures all count readmission, the EDAC measures provide patients a more comprehensive and patient-centered perspective on the 30-day post-discharge experience. The Medicare spending measure (that is, MSPB measure) assess the payments made for care providing insight into costs, but do not directly assess the days that patients spend in an acute care setting following hospital discharge. For the Hospital IQR Program, hospitals would submit Medicare administrative claims for calculation of the EDAC measures, and regardless of the outcome of that data, hospitals would receive credit for submitting the information under the Program. Therefore, we do not believe hospitals would be ''penalized'' as they are not being asked to submit additional information and payment will not be adjusted based on results of these measures.

We understand that commenters have concerns about the interaction between Medicare payment policy regarding admissions spanning two midnights and the EDAC measures. However, the EDAC measures aim to capture all post-discharge acute care days, regardless of whether they are considered outpatient or inpatient. Therefore, the ''2-midnight'' policy or any changes to such policy will not influence the outcome of these measures, as all post-discharge days in acute care are captured whether they are billed as outpatient or inpatient days.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45155 through 45157) and final rule with comment period (77 FR 68426 through 68433), we expressed concern about recent increases in the length of time that Medicare beneficiaries spend as hospital outpatients receiving observation services. Subsequently, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we addressed several of these concerns through changes in

Medicare's policies regarding payment of hospital inpatient services under Part B, as well as the appropriateness of Part A payment for short hospital stays (that is, the ''2-midnight'' policy). In so doing, we clarified that Part A payment is appropriate for admissions where the medical record supports the admitting physician's determination that the beneficiary either requires care at a hospital expected to transcend at least 2 midnights or that the stay will involve a procedure designated by the OPPS Inpatient-Only list as an inpatient-only procedure (or meets some other CMS designated exception). The ''2-midnight'' policy is a payment policy and does not limit or direct medical decision making.

At the same time, we imposed a moratorium on Recovery Auditor reviews related to patient status, which has been extended to impact dates of service spanning October 1, 2013 through September 30, 2015. In our CY 2016 OPPS/ASC proposed rule (80 FR 39350), we announced our plans to limit future Recovery Audit reviews surrounding patient status to providers with high denial rates, as determined through patient reviews conducted by CMS Quality Improvement Organizations, related to Part A payment policies for inpatient admission. In addition, Recovery Auditor patient status reviews will be performed under an abbreviated look-back period, if the provider bills the claim within 3 months of the date of service, to provide increased opportunities for denied Part A claims to receive inpatient Part B payment. We believe such ongoing and future initiatives address the commenters' concerns regarding extended observation.

Comment: Many commenters opposed the addition of the EDAC measures. One commenter acknowledged CMS' rationale for adoption to prevent hospitals keeping patients in observation units or the ED to avoid them being counted in the 30-day readmission measure, but argued that there are other factors that could account for the observed variability that cannot be captured in claims data and will not be considered in calculating or risk-adjusting. The commenters noted that hospitals serving a disproportionate share of disadvantaged patients may face higher readmission rates or excess days due to conditions beyond the hospitals' control.

Response: The goal of these measures is not to prevent hospitals from keeping patients in the ED or observation units; it is to help patients and providers understand variation among hospitals in the days that are spent by patients in acute care settings following a discharge for AMI and HF. The measures provide a broader perspective on post-discharge events than the current readmission measures and are intended to incentivize improvements in care transitions from the hospital so that patients are less likely to return to the acute setting.

Although the measures cannot capture all reasons for variability among hospitals, the EDAC measures incorporate risk adjustment using claims data to account for patient factors that could account for the observed variability. The measures use claims-based risk adjusters that are clinically relevant and have strong relationships with the outcome as has been done in other claims-based outcome measures in the Hospital IQR Program. This approach was supported by the TEP. As part of regular measure reevaluation, we monitor ongoing hospital performance to evaluate if certain hospitals are negatively affected by the measures.

Comment: Some commenters recommended that CMS not adopt the EDAC measures, noting that the publicly displayed measure data may not be useful to beneficiaries and that it is unclear if performance on the measure indicates better outcomes. One commenter opposed the proposed adoption of the EDAC measures because these measures combine day counts for readmissions, observation stays, and ED visits.

Response: We agree that the EDAC measures alone will not provide a complete picture of quality on all outcomes for a given hospital. However, we disagree that data from this measure would not be useful to beneficiaries. We believe that it is important to provide more information so that the public can look at results in conjunction with those of other quality measures, such as the readmission and mortality measures, to gain a more comprehensive view of the quality of care at a hospital. Our discussions with patients and the TEP, as well as published literature, indicate that acute care utilization after discharge (that is, return to the ED, observation stay, and readmission), for any reason, is disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections and complications. These measures are meant to provide patients with a more complete picture of potential post-discharge acute care use as they make choices for their care.

Regarding whether better performance indicates better outcomes, we disagree that it is unclear whether performance on the measure indicates better outcomes. We are confident that for most patients, remaining home or remaining in a non-acute setting rather than returning to the hospital indicates a better outcome. Although some hospital returns are unavoidable, others may result from poor quality of care, overutilization of care or inadequate transitional care. Transitional care includes effective discharge planning, transfer of information at the time of discharge, patient assessment and education, and coordination-of-care and monitoring in the post-discharge period. When appropriate care transition processes are in place (for example, a patient is discharged to a suitable location, communication occurs between clinicians, medications are correctly reconciled, timely follow-up is arranged), fewer patients return to an acute care setting, either for an ED visit, observation stay, or hospital readmission during the 30 days post-discharge. Numerous studies have found an association between quality of inpatient or transitional care and early (typically 30-day) readmission rates [206] [207] [208] [209] [210] [211] [212] [213] [214] and ED visits [215] [216] [217] [218] [219] for a wide range of

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conditions including AMI and heart failure.

Regarding the commenters concern about combining the count of days for readmissions, observations stays or ED visits, we note that all acute care utilization is not equal in its disruption, cost or risk to patients. Longer returns to the hospital are more disruptive and impart greater risk to patients, and often represent greater severity of illness on return. This is why the EDAC measures' outcomes are expressed in days. We believe from a patient perspective it is the count of total days that is most meaningful and representative of the disruption. This is also why we combine day counts for each type of event and do not separately report rates of each type of event. This is also valuable for hospitals, because a hospital with a high number of ED visits may still be able to achieve a low number of total days in acute care by actively coordinating care from the ED and avoiding rehospitalizations. The measure combines these three visit types based on the concept that the rate of each type of event is not as relevant to patients as the total days that they spend in acute care settings.

Comment: Many commenters opposed the proposal to adopt the EDAC measures, because they believed that these measures should be NQF-endorsed before being proposed for the Hospital IQR Program.

Response: We proposed to include these non-NQF-endorsed measures under the Hospital IQR Program exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act. Although the proposed measures are not currently NQF-endorsed, we considered available measures that have been endorsed or adopted by the NQF. We also are not aware of any other similar measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

We note that the EDAC measures will be submitted to NQF with appropriate consideration for SDS, if required, for endorsement proceedings once an appropriate measure endorsement project has a call for measures. We believe it is important to move forward with these measures in this program because they fill an important measurement gap. These measures address measurement gaps by including a range of outcomes that are important to patients (that is, readmissions, ED visits, and observation stays), by capturing the total amount of time patients spend in acute care, and by accounting for time at risk of an event (that is, survival time). We anticipate that the measures will support hospital efforts to further optimize quality of care, particularly the quality of transitional care, by providing a more comprehensive picture of post-discharge events. The measures will also provide more detailed information to consumers on what to expect following discharge. These measures also addresses the NQS priority of care coordination. The MAP conditionally supported these measures. Some MAP members noted these measures could help address concerns about the growing use of observation stays.

Comment: Some commenters opposed the proposed inclusion of the EDAC measures. One commenter noted that the proposed measures would include emergency department visits and observation stays, yet there is no consistent evidence to suggest that either is being substituted for readmissions by hospitals. One commenter noted that the proposed EDAC measures suggest that CMS is dismissive of the importance of hospital-level care and has reservations with the use of observation services to avoid a readmissions policy.

Response: The commenters suggested that the EDAC measures may have been developed out of concern for the use of observation stays in lieu of readmission without evidence that either are being substituted for readmissions. However, we did not develop these measures to primarily capture substitutions for readmissions; we developed these measures to provide a broad perspective on post-discharge events. The measures are intended to incentivize improvements in care transitions from the hospital so that patients are less likely to return to the acute setting unnecessarily.

We do not dismiss the importance of hospital-level care and support hospitals using the level of care most appropriate for each particular patient's condition. Some returns to the acute care setting are necessary and the goal is not to avoid all post-discharge acute care service utilization. However, acute care utilization after discharge (that is, return to the ED, observation stay, and readmission), for any reason, is disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections and complications. When appropriate care transition processes are in place (for example, a patient is discharged to a suitable location, communication occurs between clinicians, medications are correctly reconciled, timely follow-up is arranged), fewer patients return to an acute care setting, whether for an ED visit, observation stay, or hospital readmission during the 30 days post-discharge. Numerous studies, which we cited in response to other comments, have found an association between quality of inpatient or transitional care and early (typically 30-day) readmission rates, and ED visits for a wide range of conditions including AMI and heart failure.

Comment: One commenter expressed concern that physicians, not hospitals, dictate discharge date.

Response: It is often true that physicians determine the discharge date for patients. However, the EDAC measures are intended to support broad efforts by both physicians and hospitals to improve the transitions of care from acute care at the time of discharge to reduce the likelihood of patients' needing to quickly return to the acute care setting. Hospitals can work with physicians to reduce the likelihood of unnecessary returns to the hospital in the immediate post-discharge period. The EDAC measures are not intended to penalize hospitals for extended stays. The measures are intended to help patients and providers understand variation among hospitals in the days that are spent by patients in acute care settings following a discharge for AMI and HF.

Comment: One commenter opposed the proposed inclusion of the EDAC measures and noted that the measures are unduly burdensome to inpatient and outpatient providers as well as CMS.

Response: For the EDAC measures, there is no data collection burden for inpatient or outpatient providers because we calculate the measures using administrative claims data. Our hope is that the information provided to hospitals through these measures will help inpatient and outpatient providers better understand the trajectory of care

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emergency department overcrowding. Academic emergency medicine: official journal of the Society for Academic Emergency Medicine. Nov 2001;8(11):1091–1094.

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for patients that have been discharged from their facility, including acute care visits to other sites, and will assist in targeting quality improvement activities aimed at improving transitions of care.

Comment: One commenter acknowledged the responsibility of the hospital in managing the patient through the transitions of care, but expressed concerns that patient anonymity and freedom of choice in the pursuit of post-acute care are factors to be concerned about.

Response: We agree with the commenter and recognize that patients' choices will influence post-acute patterns of care. Patients choose where to receive post-discharge care, and some patients may elect to seek care in the acute care setting, for example, going to the emergency department rather than an outpatient physician office. However, as the commenter mentioned, there are actions hospitals can take to decrease the likelihood that patients will feel a need to seek acute care in the days following discharge. Actions taken by hospital staff while preparing to transition the patient to outpatient status can minimize a patient's risk for adverse outcomes, as can collaboration and communication between the inpatient and outpatient providers within a community. Measuring excess days in acute care will support existing incentives to invest in interventions to improve hospital care, better assess the readiness of patients for discharge, and facilitate transitions to outpatient status.

We do not believe this measure will limit patient anonymity in any fashion. We also note that the measure does not pose additional risks to patient confidentiality because the measure is based on claims data already collected.

Comment: Some commenters had significant reservations about composite measures and patients' ability to understand them, as well as providers' ability to take meaningful actions that would have an impact on patient outcomes.

Response: We have developed the EDAC measures to try to provide important patient-centered information. We clarify that although care in multiple different settings is included in the outcome, the EDAC measures are not composite measures, meaning that they do not include distinct measures that are combined. Instead, each of the EDAC measures is a single outcome measure that is meant to be conceptually straightforward. The measures indicate how many more (or fewer) days patients from a particular hospital spend in acute care following discharge than would be expected at an average hospital. Our hope is that beneficiaries will find this helps to provide a more complete picture of post-discharge outcomes. We will aim to present results of these measures in a straightforward manner on *Hospital Compare* for consumers to more easily understand. In addition, we disagree that providers do not have the ability to take meaningful actions that would have an impact on patient outcomes as a result of these measures. We believe that these measures, which evaluate excess days in acute care, will support existing hospital incentives to further invest in interventions to improve hospital care, better assess the readiness of patients for discharge, and facilitate transitions to outpatient status.

Comment: Some commenters opposed the proposal to adopt the EDAC measures and stated that the measures ignore external factors, outside of a hospital's or clinician's control, and conflate the correlation between fewer post-discharge encounters and higher quality care. The commenters recommended that CMS work to fine-tune the proposed measures and consider moving away from all-cause measures to reflect the fact that certain readmissions specific to the initial encounter can be managed better than others.

Response: We recognize that some hospital returns are unavoidable and outside of a clinician or hospital's control. However, as previously noted, other returns may result from poor quality of care, overutilization of care or inadequate transitional care. Transitional care includes effective discharge planning, transfer of information at the time of discharge, patient assessment and education, and coordination of care and monitoring in the post-discharge period. When appropriate care transition processes are in place (for example, patient is discharged to a suitable location, communication occurs between clinicians, medications are correctly reconciled, timely follow-up is arranged, etc.), fewer patients return to an acute care setting, either for an ED visit, observation stay, or hospital readmission during the 30 days post-discharge. Numerous studies, which we cited in response to other comments, have found an association between quality of inpatient or transitional care and early returns to the hospital.

We will continue to fine-tune the measure as we do with all measures, through the process of annual measure reevaluation. However, we measure all-cause acute care utilization for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. Second, limiting the measures to acute care utilization for HF exacerbation and AMI may make them susceptible to gaming. Moreover, it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit. Measuring all-cause acute care utilization encourages hospitals to evaluate the full range of factors that increase the risk of a patient's return to the acute care setting.

Comment: One commenter opposed the proposed adoption of the proposed EDAC measures, noting the lack of transparency in their development.

Response: We do not agree that we developed these measures with a lack of transparency. We developed the measures in accordance with established measure development guidelines, and through assessment by external groups, a public comment period prior to the proposed rule, and a TEP of national experts and stakeholder organizations. In addition, the proposed measures were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014'' [220] in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2015 Final Recommendations.[221] The MAP conditionally supported the EDAC measures. We have also posted the measures' methodology reports on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: One commenter expressed concern with the decision to equate the costs and intensity in observation and emergency department care with that of inpatient care when they are treated differently for payment purposes. The commenter specifically disagreed with counting ED visits as half days, because the majority of ED visits last much less time than that.

Response: We appreciate the commenter's concern about equating the cost and intensity of observation and ED care with that of inpatient care. Acute care utilization after discharge (that is,

[220] Measure Applications Partnership: List of Measures Under Consideration (MUC) for December 1, 2014. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318*.

[221] National Quality Forum ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx* and ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/*.

return to the ED, observation stay, and readmission), for any reason, is disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections and complications. We agree that all acute care utilization is not, however, equal in its disruption, cost, or risk to patients. Prolonged intensive care is worse from a patient perspective than a brief ED visit. That is why we elected to report each of the EDAC measures as a count of days: Events lasting longer with more cost and disruption (such as readmissions) therefore, naturally weigh more than brief events (such as ED visits) in the overall day count.

We appreciate the commenter's feedback on considering ED treat-and-release visits as half a day. The average length of stay for a treat-and-release patient from the ED is approximately four hours. Thus, we received feedback from the TEP advising that we consider a treat-and-release ED visit to be equivalent to one half day. A shorter length of stay may not capture the full burden on the patient to return to the hospital (for example, travel time and lost work time).

Comment: One commenter supported CMS' proposed EDAC measures, and concurred with the rationale. However, the commenter believed that leaving these proposed measures separate from the Hospital Readmissions Reduction Program would allow hospitals to ''game'' the Hospital Readmissions Reduction Program measures by reclassifying patients as observation stays and ED visits.

Response: We thank the commenter for the support. While we acknowledge the commenter's concern that attempts to improve EDAC measures might result in distortions in the Hospital Readmissions Reduction Program, we remind the commenter that the specific conditions for which readmissions are measured are only a small fraction of those subject to EDAC. We will continue to monitor trends to determine if there is systematic shifting and diversion of care (76 FR 51663) and will take appropriate action to minimize unintended consequences.

After consideration of the public comments we received, we are finalizing both the Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction and Excess Days in Acute Care after Hospitalization for Heart Failure measures for the FY 2018 payment determination and subsequent years as proposed.

f. Summary of Previously Adopted and Newly Adopted Hospital IQR Program Measure Set for the FY 2018 and FY 2019 Payment Determinations and Subsequent Years

The table below outlines the Hospital IQR Program measure set for the FY 2018 and FY 2019 payment determinations and subsequent years and includes both previously adopted measures and measures adopted in this final rule. We note that in past rules, we have included separate charts for each FY; however, here, we are combining the chart for the FY 2018 payment determination and subsequent years with that of the FY 2019 payment determination and subsequent years. We identify those measures that begin to be included in the program starting with the FY 2019 payment determination with a ±. In addition, all measures finalized for removal in this rule are not included in this chart.

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF No.
	NHSN	
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure. • Colon Procedures. • Hysterectomy Procedures.	0753
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
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
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
	Chart-abstracted	
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 (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
STK–04*	Thrombolytic Therapy	0437
VTE–5*	Venous Thromboembolism Discharge Instructions	N/A
VTE–6*	Incidence of Potentially Preventable Venous Thromboembolism	N/A
	Claims	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF No.
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
STK Mortality	Stroke 30-day Mortality Rate	N/A
CABG Mortality	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
COPD READMIT	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
STK READMIT	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization	N/A
CABG READMIT	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
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
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 4 (PSI/NSI)	Death among Surgical Inpatients with Serious, Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531
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
AMI Excess Days **	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	N/A
HF Excess Days **	Excess Days in Acute Care after Hospitalization for Heart Failure	N/A
Electronic Clinical Quality Measure (select at least 4)		
AMI–2	Aspirin Prescribed at Discharge for AMI	N/A
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0164
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
AMI–10	Statin Prescribed at Discharge	N/A
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	N/A
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
HTN	Healthy Term Newborn	0716
PC–01 *	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
PC–05	Exclusive Breast Milk Feeding and the Subset Measure PC–05a Exclusive Breast Milk Feeding Considering Mother's Choice.	0480
PN–6	Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	0147
SCIP-Inf-1a	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0527
SCIP-Inf-2a	Prophylactic Antibiotic Selection for Surgical Patients	0528
SCIP-Inf-9	Urinary catheter Removed on Postoperative Day 1 (POD 1) or Postoperative Day 2 (POD 2) with Day of Surgery Being Day Zero.	N/A
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–04 *	Thrombolytic Therapy	0437
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	N/A
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
VTE–3	Venous Thromboembolism Patients with Anticoagulation Overlap Therapy	0373
VTE–4	Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol or Nomogram.	N/A
VTE–5 *	Venous Thromboembolism Discharge Instructions	N/A
VTE–6 *	Incidence of Potentially Preventable Venous Thromboembolism	N/A

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF No.
Patient Survey		
HCAHPS	HCAHPS + 3-Item Care Transition Measure (CTM-3)	0166 0228
Structural		
Patient Safety Culture**	Hospital Survey on Patient Safety Culture	N/A
Registry for Nursing Sensitive Care	Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	N/A
Registry for General Surgery	Participation in a Systematic Clinical Database Registry for Registry for General Surgery	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

* Measure is listed twice, as both chart-abstracted and electronic clinical quality measure.
** Measures we are adopting beginning with FY 2018 and for subsequent years.

HOSPITAL IQR PROGRAM ADDITIONAL MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF No.
Claims		
Kidney/UTI Payment	Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure	N/A
Cellulitis Payment	Cellulitis Clinical Episode-Based Payment measure	N/A
GI Payment	Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure	N/A

8. Electronic Clinical Quality Measures

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24581 through 245820), we clarified our policy for one previously adopted voluntarily reported electronic clinical quality measure for the FY 2017 payment determination. Specifically, we clarified our requirements for the submission of STK–01 for CY 2015/FY 2017 payment determination. In addition, we proposed to expand our electronic clinical quality measure policy in order to make reporting of electronic clinical quality measures required for the FY 2018 payment determination and subsequent years.

a. Previously Adopted Voluntarily Reported Electronic Clinical Quality Measures for the FY 2017 Payment Determination

For a discussion of our previously finalized electronic clinical quality measures and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811 through 50819), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276).

b. Clarification for the Venous Thromboembolism (VTE) Prophylaxis (STK—01) Measure (NQF #0434)

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24581), we proposed to clarify reporting requirements for the Venous Thromboembolism (VTE) Prophylaxis (STK—01) Measure (NQF #0434). In the FY 2016 IPPS/LTCH PPS final rule (78 FR 50808), we stated that hospitals need not report the STK–01 measure as part of the STK measure set if reporting electronically, because no electronic specification existed for STK–01. In other words, hospitals that successfully submit STK–02, STK–03, STK–04, STK–05, STK–06, STK–08, and STK–10 as electronic clinical quality measures are not required to also chart-abstract and submit STK–01 in order to meet Hospital IQR Program requirements for the FY 2016 payment determination. However, hospitals that do not submit the specified electronic clinical quality measures must continue to chart-abstract and submit STK–01 as previously required. To review the details in the 2014 IPPS/LTCH PPS final rule, we refer readers to our Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Regulations.html*.

We proposed to clarify that this policy continues for the CY 2015/FY 2017 payment determination. Hospitals that chose to submit the STK–02, STK–03, STK–04, STK–05, STK–06, STK–08, and STK–10 as electronic clinical quality measures are not required to also chart-abstract and submit STK–01 in order to meet Hospital IQR Program requirements for the FY 2017 payment determination. However, hospitals that do not submit the specified electronic clinical quality measures must continue to chart-abstract and submit STK–01 as previously required. We note that STK–01 is proposed for removal for CY 2016/FY 2018 payment determination and refer readers to section VIII.A.3.b. of the preamble of this final rule for more details.

We invited public comment on this proposal.

Comment: One commenter supported the idea that hospitals that successfully submit STK–02, STK–03, STK–04, STK–05, STK–06, STK–08, and STK–10 as electronic clinical quality measures would not be required to also chart-abstract and submit STK–01 in order to meet the Hospital IQR Program requirements for the FY 2016 payment determination.

Response: We thank the commenter for its support.

Comment: One commenter expressed concern that the STK measure set lacks NQF endorsement.

Response: We disagree with the commenter because STK–08 is the only STK measure that has lost endorsement.[222] STK 02, STK–03, STK–04, STK–05, STK–06, and STK–10 are still currently endorsed. The stroke measures are stewarded by The Joint Commission, and to our knowledge, The Joint Commission is not planning to resubmit STK–08 for re-endorsement. Despite the fact that STK–08 has lost endorsement, we still believe it should remain in the Hospital IQR Program at

[222] ''Neurology Endorsement Maintenance—Phase I Technical Report,'' pages 72–73, available at: *http://www.qualityforum.org/Publications/2012/12/Neurology_Endorsement_Maintenance_-_Phase_I_Technical_Report.aspx*.

the present time to promote alignment with the EHR Incentive Program.

Comment: A few commenters recommended that both CMS and TJC consider proposing the STK–01 measure as an electronic clinical quality measure because they believed this form will allow CMS to retain the measure for voluntary reporting.

Response: We thank the commenters for their suggestion and will consider it in future rulemaking.

After consideration of the public comments we received, we are finalizing our clarification that the policy regarding STK–01 continue for the CY 2015/FY 2017 payment determination. Hospitals that chose to submit the STK–02, STK–03, STK–04, STK–05, STK–06, STK–08, and STK–10 as electronic clinical quality measures are not required to also chart-abstract and submit STK–01 in order to meet Hospital IQR Program requirements for the FY 2017 payment determination. However, hospitals that do not submit the specified electronic clinical quality measures must continue to chart-abstract and submit STK–01 as previously required.

c. Requirements for Hospitals To Report Electronic Clinical Quality Measures for the FY 2018 Payment Determination and Subsequent Years

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24581 through 24582). We proposed to expand our electronic clinical quality measure policy in order to make reporting of electronic clinical quality measures required, rather than voluntary, under the Hospital IQR Program. Specifically, we proposed that, beginning in CY 2016/FY 2018 payment determination and subsequent years, we will require hospitals to select and submit 16 electronic clinical quality measures covering three NQS domains from the 28 available electronic clinical quality measures. For the FY 2018 payment determination and subsequent years, we proposed that hospitals must submit Q3 and Q4 data for 16 measures chosen by a hospital and reported as electronic clinical quality measures. For example, for the FY 2018 payment determination, hospitals would be required to submit Q3 and Q4 CY 2016 data for 16 measures of their choice. This proposal is in alignment with the Medicare EHR Incentive Program, as discussed in section VIII.D.2.b. of the preamble of this final rule.

Hospitals would not fail validation based on these data for CY 2016/FY 2018 payment determination reporting because validation for electronic measures is currently under development. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273), we finalized a proposal to conduct a validation pilot test for electronically specified measures in FY 2015. The pilot is currently underway and therefore, the results are not yet available.

We will delay publicly reporting electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination in order to allow time for us to evaluate the effectiveness of electronically reported clinical quality measure data. In the meantime, measures reported via electronic clinical quality measure will be marked with a footnote on *Hospital Compare* noting that: (1) The hospital submitted data via EHR; (2) data are being processed and analyzed; and (3) CMS will eventually publicly report this data once CMS determines the data to be reliable and accurate.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50815 through 50818), we adopted a policy under which we would only publicly report electronic clinical quality measure data under the Hospital IQR Program if we determined that the data are accurate enough to be reported. We believe that our current proposal to delay public reporting of electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination is also in line with our existing policies. In future rulemaking, we will continue to address our intent to ensure that measures meet the reliability and validity requirements set for public reporting and that the measures are accurate and understandable before measures are publicly reported on *Hospital Compare.*

As shown in the table above entitled ''Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years,'' 6 measures (ED–1, ED–2, STK–04, VTE–5, VTE–6, and PC–01) may be reported either via chart-abstraction or as electronic clinical quality measures. For the FY 2018 payment determination and subsequent years, we proposed that hospitals may either report a full year of data (Q1 through Q4) in accordance with the submission requirements for chart-abstracted data, or electronically submit two quarters of data (Q3 and Q4) for each of these 6 measures. If hospitals chose to report these 6 measures electronically, the measures could be used to count toward the Hospital IQR Program's 16 required electronic clinical quality measures. Hospitals choosing to report these 6 measures via chart-abstraction would have to select other electronic measures to meet the requirement to report 16 electronic clinical quality measures. Additional detail on submitting electronic data for measures can be found in section VIII.A.10.d.(3) of the preamble of this final rule.

We recognize that measure rates may not be comparable between measures reported via chart-abstraction and measures that are electronically specified. Collecting electronic measure data according to our proposal that hospitals must select and submit 16 electronic clinical quality measures will help us evaluate variations in data capture modes (chart-abstracted versus electronic clinical quality measures) in order to determine whether and what adjustments are necessary for the two different modes of collection. We refer readers to section VIII.A.3.b. of the preamble of this final rule, where we discuss CMS' belief that, although the intent of a measure is the same whether it is reported via chart-abstraction or electronically, the submission modes and measure rates are not the same.

We also considered two alternative required electronic clinical quality measure reporting options. Alternative A would require hospitals to submit 10 of 28 quality measures: (1) VTE–1; (2) STK–02; (3) ED–1; (4) STK–05; (5) STK–06; (6) STK–10; (7) VTE–2; (8) STK–08; (9) ED–2; and (10) STK–03. Our data show that these measures are most frequently reported with non-zero values among hospitals attesting under 2014 Meaningful Use. In addition, all 10 of these measures have been included in the Hospital IQR Program measure set as voluntary electronic clinical quality measures since CY 2014/FY 2016 payment determination (79 FR 50209 through 50211). Alternative B would require hospitals to submit 10 of 28 quality measures of each hospital's choice. Both alternatives differ from our proposal only in the number and/or composition of the electronic clinical quality measures to be reported; that is, for both of these alternatives, the reporting periods and submission requirements would be the same as those proposed in the proposed rule.

However, we determined not to pursue these alternative reporting options as we believe that requiring hospitals to report more measures electronically is in line with our goals to move towards electronic clinical quality measure reporting and to align with the EHR Incentive Program, which requires reporting on 16 clinical quality measures covering at least three domains.

We believe that our proposals will ultimately decrease reporting burden to hospitals. Once capture is possible within EHR, the time and resources

needed to submit quality measures data are significantly less compared to manual abstraction. Electronic clinical quality measure collection does not require hospital staff time to find and pull paper medical records and manually review them to abstract data elements used in measure calculation. We acknowledge that there are initial costs, but believe that long-term benefits associated with electronic data capture outweigh those costs.

We welcomed public comment on our proposal to require hospitals to select and submit 16 electronic clinical quality measures covering three NQS domains from the 28 available electronic clinical quality measures for eligible hospitals and CAHs for the FY 2018 payment determination and subsequent years. We refer readers to section VIII.A.10.d.(3) of the preamble of this final rule for details on reporting periods and submission deadlines for electronic clinical quality measures.

Comment: Many commenters supported CMS' efforts to move towards electronic clinical quality measure reporting and to increase the number of required electronic clinical quality measures, noting the potential for electronic reporting to reduce provider burden, improve reporting efficiencies, and reduce measurement reporting costs.

Response: We thank the commenters for their support.

Comment: One commenter specifically supported the proposal to make reporting on a subset of 28 electronic clinical quality measures mandatory, but opposed CMS' proposal to allow hospitals to select among the 28 measures.

Response: We thank the commenter for its support. In order to best facilitate electronic reporting during early implementation of the requirement, we believe that allowing hospitals the flexibility to select which of the 28 electronic clinical quality measures they wish to report is necessary at this time. We will consider whether to propose a specific set of electronic clinical quality measures in future rulemaking.

Comment: Many commenters expressed concern that hospitals are not prepared to submit electronic clinical quality measures and some noted that even hospitals leading in EHR implementation face challenging vendor-level issues outside their control. Several commenters noted that electronic clinical quality measure reporting is difficult for hospitals due to the complexities involved in implementing EHRs. Some commenters noted that currently, data integration across hospitals' multiple information systems is lacking and many expressed concern that hospitals lack the resources to map the necessary data elements from the EHR to a QRDA format.

As a result of these concerns, many commenters requested an extension in the roll-out of this requirement, in order to allow hospitals time to prepare to meet reporting requirements and to allow more time for mapping and testing of this reporting approach. Many commenters recommended that CMS continue its current policy of voluntary electronic submission. Many of these commenters expressed support for CMS' goal to move towards electronic reporting, but specifically requested that CMS delay a requirement for hospitals to report electronic clinical quality measures until CY 2018, in order to align with the EHR Incentive Program. Other commenters recommended that CMS require electronic clinical quality measure reporting no sooner than CY 2017. One commenter recommended that we allow dual submission of electronic data on a voluntary basis for the Hospital IQR and EHR Incentive Programs until FY 2020.

Some commenters recommended that CMS require fewer than 16 electronic clinical quality measures. Specifically, the commenters recommended that CMS require either 2 to 3, 5, or 10 electronic clinical quality measures.

Response: We believe that requiring hospitals to report measures electronically is in line with our goals to move towards electronic clinical quality measure reporting and to align with the EHR Incentive Program. Furthermore, we believe that the CY 2016/FY 2018 payment determination is the appropriate time to require electronic clinical quality measure reporting because hospitals have had several years to report data electronically for the EHR Incentive Program and Hospital IQR Program (2 years of pilot reporting and 2 years of voluntary reporting), and because currently 95 percent of hospitals attest to successful electronic clinical quality measure reporting under the EHR Incentive Program.

However, we recognize the challenges associated with electronic reporting and encourage hospitals to work with their vendors to achieve electronic capture and reporting despite mapping and integration issues. In response to comments, we are finalizing a modification of our proposals in order to reduce the effort for hospitals with vendor challenges. We believe that requiring a lesser number of eCQMs will reduce these burdens on hospitals because the burden associated with mapping issues, which is dependent on the number of measures required to be reported, were cited as a major concern among commenters. However, we anticipate increasing this number in future rules to propose the 16 measure requirement. We believe that a full year should be enough time for hospitals to address their mapping issues and that it is important to continue to make progress towards electronic reporting.

Therefore, instead of requiring hospitals to report 16 of the 28 electronic clinical quality measures for the CY 2016/FY 2018 payment determination as proposed, we will require hospitals to report a minimum of 4 of the 28 electronic clinical quality measures for CY 2016 reporting. Suggestions from commenters ranged from 2 to 10 regarding the number of electronic clinical quality measures that should be required. We believe that requiring hospitals to report a minimum of 4 electronic clinical quality measures is reasonable because it significantly reduces burden for hospitals from the 16 proposed, but still allows us to collect data derived from EHRs to further our plans for electronic data collection and validation. Specifically, requiring only 4 electronic clinical quality measures reduces hospitals' burden of reporting by 75 percent compared to the burden of submitting 16 electronic clinical quality measures.

Further, instead of requiring hospitals to report 2 quarters of data (Q3 and Q4) two months following the reporting period as proposed, we will require hospitals to report the 4 electronic clinical quality measures for only 1 quarter (either Q3 or Q4) of CY 2016/FY 2018 payment determination, with a submission deadline of February 28, 2017. We believe this will allow more time for hospitals to overcome vendor issues, such as mapping and testing. Under this modified version of the proposals, no NQS domain distribution will be required.

Comment: One commenter requested clarification on whether it needed to report 1 year of data for the PC–01 measure via chart abstraction for the Hospital VBP Program if they report 6-months of data for PC–01 as an electronic clinical quality measure for the Hospital IQR Program.

Response: Electronic clinical quality measure submissions are not a part of the Hospital VBP Program at this time. Therefore, all hospitals must submit PC–01 measure data based on chart abstraction for that program to be included in the scoring determination, irrespective of how hospitals submit data for the Hospital IQR Program.

Comment: Some commenters requested clarification on the reporting

requirement for the eight chart-abstracted quality measures (ED–1, ED–2, PC–01, STK–4, VTE–5, VTE–6, SEP–1, IMM–2) in the Hospital IQR Program for the FY 2018 payment determination, and specifically, whether these measures must be reported via chart-abstraction if a hospital does not submit these measures electronically. (CMS notes that six of these eight measures overlap as electronic clinical quality measures, and that both the chart-abstracted and electronic versions of these measures are included in the Hospital IQR Program measure set.) Other commenters specifically asked for clarification on the reporting requirements and submission deadlines for those six Hospital IQR Program measures that can be reported either as electronic clinical quality measures, or via chart-abstraction (ED–1, ED–2, PC–01, STK–4, VTE–5 and VTE–6). One commenter asked if all six of these measures need to be reported via chart-abstraction or electronically, as a group.

Several commenters recommended allowing parallel reporting of chart-abstracted and electronically extracted measures during a transition period to ensure that eCQMs can be reported consistently, accurately and with a quality threshold. One commenter recommended that hospitals should be able to report the electronic clinical quality measures adopted under the Hospital IQR Program via chart-abstraction.

Response: We refer readers to our prior response describing modifications to our proposed policies. With respect to the ED–1, ED–2, PC–01, STK–4, VTE–5, and VTE–6 measures, instead of giving hospitals the option to either report the electronic clinical quality measure or submit via chart-abstraction as proposed, we will instead continue to require hospitals to submit data for these measures via chart abstraction as previously required, and the results of which will be publicly displayed. However, hospitals may choose to submit electronic data on any of these six measures in addition to the chart-abstraction requirements to meet the requirement to report 4 of 28 electronic clinical quality measures. This allows for parallel reporting and continued public reporting for these important quality measures.

We note that we do not agree that hospitals should be able to report all electronic measures via chart-abstraction instead, because such a policy would not further our goals to move towards electronic clinical quality measure reporting and align with the EHR Incentive Program. We also note that SEP–1, IMM–2, which are chart-abstracted measures in the Hospital IQR Program measure set, are required for reporting in order for hospitals to successfully meet program requirements.

Comment: Some commenters expressed concern that electronic clinical quality measure reporting is difficult for small hospitals due to the complexities involved in implementing EHRs. In addition, some commenters specifically requested that CMS adopt a hardship exemption, similar to the one used for under the EHR Incentive Program, to consider allowing hospitals to receive an exemption from the electronic reporting requirements if a hardship is demonstrated. One commenter noted that failure to provide an exception process will unfairly expose hospitals to risk for payment penalties.

Response: We believe that requiring hospitals to report measures electronically is in line with our goals to move towards electronic clinical quality measure reporting and to align with the EHR Incentive Program. We believe that the CY 2016/FY 2018 payment determination is the appropriate time to require electronic clinical quality measure reporting because hospitals have had several years to report data electronically for the EHR Incentive Program and Hospital IQR Program (2 years of pilot reporting and 2 years of voluntary reporting) and because currently 95 percent of hospitals attest to successful electronic clinical quality measure reporting under the EHR Incentive Program. In addition, requiring hospitals to report a minimum of 4 electronic clinical quality measures significantly reduces burden for hospitals as compared to our proposal, while still allowing us to collect statistically meaningful data to further our plans for electronic data collection.

However, we recognize the challenges associated with electronic reporting and encourage hospitals of all sizes to work with their vendors to achieve electronic capture and reporting. In response to comments and as stated above, we are finalizing a modification of our proposals in order to reduce the effort for hospitals with vendor challenges.

In addition, we will continue to allow hospitals to apply the zero denominator and case threshold exceptions described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50323 through 50324). Furthermore, we are expanding our previously established Extraordinary Circumstances Extensions/Exemptions policy (79 FR 50277) to address commenters' suggestions. We are finalizing a policy, effective starting with the FY 2018 payment determination, to allow hospitals to utilize the existing Extraordinary Circumstances Exemption (ECE) form to request an exemption from the Hospital IQR Program's electronic clinical quality measure reporting requirement for the applicable program year based on hardships preventing hospitals from electronically reporting. Such hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification). In addition, hospitals newly participating in the Hospital IQR Program, that are required to begin data submission under Hospital IQR Program procedural requirements at 42 CFR 412.140(c)(1), which describes submission and validation of Hospital IQR Program data, may also be considered undergoing hardship and can apply for an exemption. This expansion of our Extraordinary Circumstances Extensions/Exemptions policy is also discussed in section VIII.10.d.(3) of the preamble of this final rule.

Comment: Many commenters raised concerns about the reliability, feasibility, and validity of electronic clinical quality measure data reporting, noting that electronic data may not be the same as chart-abstracted data. A few commenters encouraged CMS to ensure the integrity of electronic clinical quality measures prior to requiring hospitals to report them. Some commenters recommended that CMS use the data reported for the EHR Incentive Program to provide insight on the feasibility, reliability and validity of eCQMs for future use in quality reporting programs. A few commenters also recommended that electronic clinical quality measure reporting remain voluntary until both providers and policymakers agree on the maturity of eCQM specifications and federal regulators test and validate the accuracy and completeness of electronic clinical quality measures.

Response: We note that a validation pilot is currently under way and the results of that pilot are pending, as described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273). We are requiring electronic reporting before the results of the pilot, because we believe the CY 2016/FY 2018 payment determination is the appropriate timeframe for this policy because hospitals have already had several years to report data

electronically for the EHR Incentive Program and Hospital IQR Program (2 years of pilot reporting and 2 years of voluntary reporting), and because currently 95 percent of hospitals attest to successful electronic clinical quality measure reporting under the EHR Incentive Program. We intend to use the results of this pilot to inform future rulemaking.

In addition, requiring eCQMs ensures that we will have data to address commenters' concerns regarding the comparability of electronic and chart-abstracted data. We also refer readers to section VIII.A.3.b. of the preamble of this final rule, where we discuss our position that, although the intent of a measure is the same whether it is reported via chart-abstraction or electronically, we recognize that the submission modes and measure rates are not the same.

In regards to the suggestion that we utilize data reported for the EHR Incentive Program, we appreciate commenters' suggestions, but note that hospitals have the option to report eCQMs by attestation, and 95 percent of hospitals chose to attest, under the EHR Incentive Program. Attestation data cannot inform measure validity.

We do not agree that electronic clinical quality measure reporting should remain voluntary until both providers and policymakers agree on the maturity of eCQM specifications. We believe that electronic clinical quality measures have matured since their inception,[223] and we will address any specific eCQMs in future rulemaking. Our established policies about removing or suspending measures (section VIII.A.3. of the preamble of this final rule) also apply to eCQMs.

Comment: Some commenters opposed the proposal to require hospitals to report electronic clinical quality measures and indicated concern that the proposal does not address a national goal or objective in quality improvement. The commenters also believed that reliable and accurate performance data are a higher priority than advancing a particular measure submission approach.

Response: We disagree that promoting quality measure reporting from EHRs fails to meet any goals or objectives in quality improvement. Quality measures available now, as well as those being developed for the future, are increasingly based on electronic clinical quality measure standards. In the future, we anticipate that most, if not all, quality measures will be based on data derived from EHRs. Furthermore, the move to electronic reporting is a national priority.[224] In addition, as we have explained in previous rulemaking (79 FR 50245), our aim to align the Hospital IQR Program with the Medicare EHR Incentive Program is in part so that we can attempt to minimize reporting burden on hospitals and ease the transition to reporting of electronic clinical quality measures.

Reliable, accurate data and electronic reporting are all important priorities to us. We believe that, with the advancement of technology and the use of electronic measures, even more precise, accurate, and reliable data will be captured for analysis.

Comment: Some commenters noted that CMS has not completed the validation pilot test for electronic measures, and recommended that CMS provide information on the number of hospitals that would fail to meet the Hospital IQR Program requirements because they cannot report data electronically.

Response: We anticipate completing the Hospital IQR Program electronic clinical quality measure validation pilot in 2015. Our intent is to carefully assess results of the validation pilot once available and make recommendations regarding the reporting of electronic data accordingly. In the meantime, we have observed the successes of hospitals meeting the Meaningful Use requirements. While we cannot speculate on the number of hospitals that would fail Hospital IQR Program requirements, our data show that 95 percent of hospitals already attest to successful electronic clinical quality measure reporting under the EHR Incentive Program.

Comment: Some commenters believed that the EHR Incentive Program is meant to drive electronic reporting and that requiring electronic data under the Hospital IQR Program could duplicate penalties to hospitals unable to meet Meaningful Use requirements. One commenter noted that the proposed electronic clinical quality measure policy is more aggressive than the requirements specified by either Stage 2 or Stage 3 Meaningful Use. One commenter recommended that electronic reporting should not be mandated in the Hospital IQR Program before it is required for the Meaningful Use Program.

Response: We believe that it is appropriate to require reporting from EHRs through the Hospital IQR Program because measures available now and those being developed for the future are increasingly based on electronic clinical quality measure standards. In addition, we disagree that the requirements for electronic reporting in the Hospital IQR Program duplicates penalties. In an effort to align with the EHR Incentive Program, we have specified that hospitals meeting electronic reporting requirements for the Hospital IQR Program will be considered to have successfully reported the electronic clinical quality measure requirement to the EHR Incentive Program as well. In addition, we note that our data show that 95 percent of hospitals already attest to successful electronic clinical quality measure reporting under the EHR Incentive Program and, accordingly, we do believe that the majority of hospitals will successfully report electronic clinical quality measures, meeting both the EHR Incentive Program and the Hospital IQR Program requirements. Finally, for hospitals that meet our criteria for hardship, we are expanding our Extraordinary Circumstances Extensions/Exemptions policy as discussed above.

Comment: One commenter recommended that there should be consideration given to hospitals that do not have 16 non-zeros to report.

Response: We refer readers to our modified policy described above. We expect hospitals to make every effort to report at least 4 electronic CQMs by February 28, 2017 since this is a Hospital IQR Program requirement. Hospitals that meet this requirement will be considered to have successfully reported. In addition, as is permitted under the EHR Incentive Program (79 FR 50323 through 50324), the zero denominator and case threshold exceptions apply to electronic reporting under the Hospital IQR Program (79 FR 50258). We also clarify here that we interpret ''non-zeros'' to be measures for which a hospital has at least one patient meeting the measure inclusion requirements.

Comment: Some commenters indicated that the resources required to establish functionality to produce QRDA files are limited due to other high-priority initiatives, including implementation of ICD–10 in October 2015. In addition, some commenters noted the learning curve associated with the transition to ICD–10 may impact the quality of electronic data.

Response: We note that while ICD–10 goes into effect October 1, 2015, we are not requiring submission of electronic clinical quality measure data until February 28, 2017. We believe that this

[223] *https://ecqi.healthit.gov/eh.*

[224] HHS Health Resources and Services Administration: *http://www.hrsa.gov/healthit/meaningfuluse/MU%20Stage1%20CQM/index.html.*

provides hospitals with ample time to prepare to submit electronic data.

Comment: One commenter recommended that the proposed electronic clinical quality measure requirement be delayed until the 2014 Edition EHR technology is made widely available to hospitals.

Response: While there may be varying levels of accessibility as a result of a hospital's available resources, the 2014 Edition of CEHRT is currently already widely available to hospitals.[225]

Comment: Some commenters recommended that CMS adopt the recommendations for streamlining national quality measurement efforts outlined in the Institute of Medicine's Vital Signs report.

Response: We thank the commenters for their recommendation and will consider this approach for future rulemaking. In addition, we refer readers to the Institute of Medicine's Vital Signs report for more information.[226]

Comment: Several commenters encouraged CMS to engage stakeholders to develop a plan to transition to electronic reporting.

Response: We thank the commenters for their recommendation and note that we engage with stakeholders throughout the year through monthly calls with associations, vendors, and hospitals. We are nearing our fourth annual eCQM kaizen event where selected subject matter experts gather to apply Lean principles [227] to further the evolution of these measures. We are aware that our external stakeholders would like information on how the Lean methodology has been applied to the development of electronic clinical quality measures (eCQMs). Therefore, we are in the process of identifying a central Web site where the public can access information resulting from the events we have conducted with internal and external stakeholders. There will be an announcement on the eCQI Resource Center when this information is ready for viewing (*https://ecqi.healthit.gov/*).

Comment: Some commenters suggested that electronic measures not be finalized until they have been endorsed by NQF.

Response: We refer readers to our table of eCQMs in section VIII.A.7. of the preamble of this final rule, above, for which measures are currently considered endorsed as eCQMs. We refer to these eCQMs as ''legacy'' eCQMs because they were re-specified as eCQMs after first being collected in chart abstracted form. These legacy eCQMs are considered endorsed until their next re-endorsement cycle. In communications with NQF, CMS and other measure stewards such as TJC were directed to submit the legacy eCQMs for endorsement during maintenance review in order for NQF to continue to consider the eCQM versions endorsed. We will take this information into consideration as our measures are due for their maintenance re-endorsement.

Comment: One commenter expressed concern that we do not have the infrastructure to accept patient-level data. Another commenter noted their concern that 2015 is the first year electronic QRDA I submission has been accepted by CMS.

Response: We note that 2015 is not the first year CMS has requested electronic QRDA I submission. As described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50905), electronic reporting pilots for the EHR Incentive Program from 2012 and 2013 included electronic reporting via QRDA I. In addition, as described above, we note that we are specifically delaying required electronic clinical quality measure reporting until Q3 or Q4 of CY 2016 for the FY 2018 payment determination with a submission deadline of February 28, 2017 in order to provide hospitals with additional time to implement any necessary software. We refer readers to section VIII.A.10.d. of the preamble of this final rule for additional detail on our QRDA requirements.

Comment: Some commenters expressed concern about the public reporting implications of electronic data for hospitals in future years. These commenters noted that the proposed delay of public reporting acknowledges problems with electronic data accuracy.

Response: Because we currently do not have results available from the validation pilot, we cannot yet comment, either negatively or positively, on the implications of public reporting of electronic data. Our intent is to assess results of the validation pilot once available and make recommendations regarding the reporting of electronic data accordingly. We note that we will propose plans to publicly display electronic data in next year's rulemaking, after the conclusion and assessment of the validation pilot. This timing would enable us to finalize public display details prior to the February 28, 2017 deadline for electronic clinical quality measure data submission.

Comment: Some commenters noted their belief that the Hospital IQR Program is not aligned with TJC's core measure set and stated that the lack of quality measure harmonization and alignment creates inefficiencies and serves as a source of confusion. The commenters recommended that CMS align the electronic clinical quality measure set with the TJC core measure set.

Response: We appreciate the commenters' promotion of measure alignment and will review TJC's core measure set to assess future potential for measure alignment opportunities. However, in doing so, we must consider external alignment with CMS' policy goals, including alignment with other CMS programs, CMS quality reporting programs, the EHR Incentive Program, and supporting efforts to move facilities towards reporting electronic measures. The Hospital IQR Program's requirements as finalized further our priorities while keeping hospital burden in mind.[228]

Comment: One commenter requested that CMS name e-measures distinctly, such that chart-abstracted or claims based measures will not be confused with these measures.

Response: We acknowledge the commenter's concern around clear identification of electronic measures. Measures derived from EHRs are currently referred to as eCQMs (electronic clinical quality measures). We will take commenter's suggestion into consideration.

Comment: One commenter noted its concern that the time required to complete electronic document templates is already burdensome and has impacted the amount of time providers have available for direct patient interaction. Rapidly increasing the amount of structured data required in order to support fully electronic clinical quality measure reporting would dramatically increase that burden.

Response: We recognize the commenter's concern and we continue to work with stakeholders, specifically providers, to alleviate burden where possible. Once full data capture is possible within EHR, the time and resources needed to submit quality measures data are significantly less compared to manual abstraction.

[225] 2014 CEHRT. Retrieved from: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/CEHRT2014_FinalRule_QuickGuide.pdf.*

[226] IOM: Vital Signs: Core Metrics for Health and Health Care Progress—See more at: *http://iom.nationalacademies.org/Reports/2015/Vital-Signs-Core-Metrics.aspx#sthash.34FRrBZZ.pdf.*

[227] ASQ: Lean Six Sigma in Healthcare. Available at: *http://asq.org/healthcaresixsigma/lean-six-sigma.html.*

[228] Conway, P. The Core Quality Measures Collaborative: A Rationale And Framework For Public-Private Quality Measure Alignment. Health Affairs Blog, June 23, 2015.

After consideration of the public comments we received, we are finalizing a modified version of our proposal. Specifically, instead of requiring hospitals to report 16 electronic clinical quality measures as proposed, we are finalizing that hospitals must report at least 4 electronic clinical quality measures. However, we intend to propose to increase the number of required electronic clinical quality measures in the FY 2017 IPPS/LTCH PPS proposed rule, as hospitals should have sufficient time to address the mapping issues by February 2017. In addition, instead of requiring that hospitals select and report electronic clinical quality measures across three NQS domains as proposed, under our finalized policy, we will not require that any of the 4 electronic clinical quality measures fall under any particular NQS domain.

Furthermore, instead of requiring two quarters of electronic clinical quality measure data (Q3 and Q4 of CY 2016) for the FY 2018 payment determination (CY 2016 reporting), we are finalizing that hospitals must submit electronic clinical quality measure data for only one quarter, either Q3 or Q4, of CY 2016 for the FY 2018 payment determination by February 28, 2017. We also note that, although we proposed to allow hospitals to report 6 measures (ED–1, ED–2, PC–01, STK–4, VTE–5, and VTE–6) either via chart-abstraction or electronically, these measures will remain required via chart-abstraction as previously required. However, hospitals may choose to submit electronic data, in addition to chart-abstracted data, on any of these 6 measures to meet the requirement to report 4 of 28 electronic clinical quality measures.

Finally, while we proposed that measures reported via electronic clinical quality measure would be marked with a footnote on *Hospital Compare,* we are finalizing instead that any data submitted electronically will not be posted on the *Hospital Compare* Web site. We will address public reporting of electronic data in next year's rulemaking, after the conclusion and assessment of the validation pilot.

9. Future Considerations for Electronically Specified Measures: Consideration to Implement a New Type of Measure That Utilizes Core Clinical Data Elements

a. Background

We have implemented several claims-based measures comparing hospital performance on 30-day mortality, 30-day readmission, and complications following hospitalization for several conditions and procedures in the Hospital IQR, Hospital Readmissions Reductions, and Hospital VBP Programs. Although these measures have been shown to provide valid information about hospital performance, the clinical community continues to express the opinion that data gathered directly from patients and used by clinicians to guide diagnostic decisions and treatment are preferable for risk adjustment of hospital outcome measures. In response to clinicians and providers' feedback in public comment periods during measure development, and keeping with our goal to move toward the use of electronic health records (EHRs) for electronic quality measure reporting throughout CMS programs, where feasible, we are considering: (1) The use of core clinical data elements derived from EHRs for use in future quality measures (for example, risk adjustment of outcome measures); (2) the collection of additional administrative linkage variables to link a patient's episode-of-care from EHR data with his administrative claim data, and (3) use of content exchange standards.

During a July 2014 public comment period on the CMS Call for Public Comment Web site [229] for the hybrid hospital-wide readmission measure with administrative claims and electronic health record data, we received supportive feedback on the importance of the use of clinical data in hospital outcome measures. Commenters supported our efforts in examining new approaches to provide a more accurate assessment and portrayal of services provided by clinicians and hospitals, and the feedback also indicated their belief that it is very important that enriched clinical data from an EHR be used to supplement the clinically limited datasets available from administrative claims data. We note that reviewers can find the public comment summary report within the Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1), in the ''Downloads'' section of our Measure Methodology Web page. We refer readers to the Core Clinical Data Elements and Hybrid Measures zip file found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

In response to this public feedback, as well as CMS policy goals, we have identified a set of 21 clinical variables, or core clinical data elements, which we note are routinely collected on hospitalized adults and feasibly extracted from hospital EHRs. We believe that these core clinical data elements can be adapted for future use as part of specific quality measures. During our testing, we found that these 21 core clinical data elements can be used to risk adjust 30-day mortality and 30-day readmission outcome measures. Although we have thus far only tested the core clinical data elements for use in the risk adjustment models of hospital-level outcome measures, they could be utilized in other ways in the future. We anticipate that EHRs will continue to improve capturing of relevant clinical data and we also anticipate future expansion of the list of core clinical data elements.

In the future, one way in which we envision using core clinical data elements in conjunction with other sources of data, such as administrative claims, is to calculate ''hybrid'' outcome measures, which are quality measures that utilize more than one source of data. We believe that these types of hybrid measures could enhance the current CMS administrative claims-based outcome measures by utilizing patient clinical data captured in the EHR. We have shown that core clinical data elements captured in EHRs and used to risk adjust hospital outcome measures improve the discrimination of the measures, or the ability to distinguish good and poor performers, as assessed by the c-statistic, which evaluates the measure's ability to discriminate or differentiate among high and low performing hospitals.[230] [231] [232] Finally, hybrid measure results would need to be calculated by CMS to determine hospitals' risk-adjusted rates relative to national rates used in public reporting. With hybrid measures, hospitals would forward data extracted from the EHR, and CMS would perform the measure calculations.

To illustrate one way in which the 21 core clinical data elements can be used, we developed two hybrid measures: (1) Hospital 30-Day Risk-Standardized

[229] CMS.gov. Measure Management System, Public Comment. Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html.*

[230] Hybrid 30-Day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1).

[231] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1).

[232] 2013 Core Clinical Data Elements Technical Report (Version 1.1).

Acute Myocardial Infarction (AMI) Mortality eMeasure (NQF #2473); and (2) a hybrid hospital-wide 30-day readmission measure, which has not yet undergone NQF endorsement proceedings. However, the latter measure's development was encouraged by the MAP.[233] We note that the 2013 Core Clinical Data Elements Technical Report Version 1.1 (a methodology report) provides a more detailed review of the clinical core data elements. This document is posted on our Measure Methodology Web page, under the ''Downloads'' section in Core Clinical Data Elements and Hybrid Measures zip file, available on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

b. Overview of Core Clinical Data Elements

Core clinical data elements are a set of clinical variables derived from EHRs that can be used to risk adjust hospital outcome measures. We have currently identified a set of 21 core clinical data elements that: (1) Can be feasibly extracted from current EHR systems; (2) are available on most adult patients; and (3) are relevant to patient outcomes following hospitalization. These core clinical data elements are listed in the table below.

CURRENTLY IDENTIFIED CORE CLINICAL DATA ELEMENTS CONSIDERED FOR RISK-ADJUSTMENT OF HYBRID OUTCOME MEASURES USED IN THE HOSPITAL SETTING

Data elements	Units of measurement	Time window for first captured values
Patient Characteristics		
Age at admission	Years	—
Gender	Male or female	—
First-Captured Vital Signs		
Heart Rate	Beats per minute	0–2 hours.
Systolic Blood Pressure	mmHg	0–2 hours.
Diastolic Blood Pressure	mmHg	0–2 hours.
Respiratory Rate	Breath per minute	0–2 hours.
Temperature	Degrees Fahrenheit	0–2 hours.
Oxygen Saturation	Percent	0–2 hours.
Weight	Pounds	0–24 hours.
First-Captured Laboratory Results		
Hemoglobin	g/dL	0–24 hours.
Hematocrit	% red blood cells	0–24 hours.
Platelet	Count	0–24 hours.
WBC Count	Cells/mL	0–24 hours.
Potassium	mEq/L	0–24 hours.
Sodium	mEq/L	0–24 hours.
Chloride	mEq/L	0–24 hours.
Bicarbonate	mmol/L	0–24 hours.
BUN	mg/dL	0–24 hours.
Creatinine	mg/dL	0–24 hours.
Glucose	mg/dL	0–24 hours.
Troponin	ng/mL	0–24 hours.

This set of core clinical data elements consists of the first captured vital signs, and the results of a complete blood count and basic chemistry panel. These core clinical data elements were selected because they were empirically shown to be captured during routine clinical practice on most adult hospitalized patients.[234] Among other ways, one way in which we envision using these core clinical data elements is to risk adjust outcomes measures, since the elements improve the discrimination of hospital outcome measures as assessed by c-statistic and enhances the face validity of measures for the clinical community, which continue to express a preference for these types of data to account for patients' severity of illness.[235]

In the context of risk-adjustment, future hybrid measures would utilize some or all of the 21 core clinical data elements listed above, as well as any future feasible core clinical data elements. For example, the Hospital 30-day Risk-Standardized Acute Myocardial Infarction (AMI) Mortality eMeasure (NQF #2473) uses five core clinical data elements: Age; heart rate; systolic blood pressure; troponin; and creatinine.[236] In contrast, the hybrid hospital-wide measure uses 14 of the 21 core clinical data elements (age, heart rate, respiratory rate, temperature, systolic blood pressure, oxygen

[233] National Quality Forum. Measure Application Partnership. Available at: *https://share.cms.gov/center/CCSQ/QMHAG/DHMM/Measures%20Development%20and%20Maintenance/map/MAP%202014/MAP%202015/map_pre-rulemaking_final_report_2015.pdf.* Accessed on February 5, 2015.

[234] 2013 Core Clinical Data Elements Technical Report (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[235] Hybrid 30-day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1) and Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[236] Hybrid 30-day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

saturation, weight, hematocrit, white blood cell count, sodium, potassium, bicarbonate, creatinine and glucose).[237] These two hybrid measures illustrate how specific core clinical data elements used in a given hybrid measure will vary depending on the core clinical data elements identified as relevant for and predictive of that measure outcome in the target cohort.

We note that the 21 core clinical data elements included are already routinely recorded in the EHR by clinical staff at the beginning of an inpatient encounter to diagnose and treat patients. Collection of these core clinical data elements are in response to stakeholder preference, and in particular, for the use of clinical information in risk models, but is not meant to guide or alter the care patients receive. We believe clinical staff should continue to only perform measurements or tests that are appropriate for diagnostic assessment or treatment of patients.

We assessed the feasibility of extraction of the 21 core clinical data elements in models of readmission and mortality outcome measures (Core Clinical Data Elements Development is discussed below). For additional detail on testing and the measure methodologies, we refer readers to the 2013 Core Clinical Data Elements Technical Report Version 1.1 methodology report posted on our Measure Methodology Web page, under the ''Downloads'' section in Core Clinical Data Elements and Hybrid Measures zip file, on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

c. Core Clinical Data Elements Development

To identify this set of core clinical data elements, we first focused on those data elements that can be used to risk adjust hospital outcome measures. We developed a systematic five-step approach in which we: (1) Established a set of criteria to assess the feasibility of consistently identifying and extracting EHR data elements, and convened a diverse group of health information technology experts and end users to apply these criteria to EHR data; (2) conducted a systematic review of the literature to identify clinical data that has been shown to predict patient outcomes following acute care hospital admissions; (3) assessed the frequency and timing of capture of candidate data elements using a dataset from an active EHR data warehouse of a large healthcare system serving over 3.3 million beneficiaries; [238] (4) tested the utility of feasible data elements in risk-adjusted hierarchical models of 30-day mortality following hospitalization for a variety of common and costly medical conditions (for example, heart failure, pneumonia, and stroke); and (5) tested the core clinical data elements as risk-adjustment variables in the previously adopted Hospital IQR Program measure, CMS 30-Day Hospital-Wide All-Cause Unplanned Readmission Outcome measure (NQF #1789) finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528), creating the hybrid hospital-wide readmission measure. These steps are discussed in more detail below.

To identify and test the core clinical data elements, a TEP was convened. TEP members applied feasibility criteria to each data type in the Quality Data Model (QDM) considering the context of adult hospitalized patients only. The QDM is an information model that provides a standardized description of the clinical information captured in EHRs, and provides a uniform framework to support quality measurement that utilizes EHR data. TEP members were asked to indicate whether at least one data element within each data type was: (1) Consistently obtained in the target population (patients 18 years and older) based on current clinical practice; (2) captured with a standard definition and recorded in a standard format within the EHR; and (3) entered in structured fields that are feasibly retrieved from current EHR systems.

Next, we conducted a systematic review of the literature to identify clinical data shown to be predictive of mortality and readmission in statistical models. A thorough review of studies revealed that several categories of clinical information from patient medical records captured during diagnostic assessment and treatment were commonly used to predict mortality and readmission. These included, but were not limited to, basic demographic information, laboratory test results, and vital sign findings. The results are described in the 2013 Core Clinical Data Elements Technical Report (Version 1.1) and is available on our Measure Methodology Web page, under the ''Downloads'' section in Core Clinical Data Elements and Hybrid Measures zip file found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

In order to empirically establish the feasibility of potential clinical data elements identified by the TEP, we used a large multi-site database from a healthcare system serving over 3.3 million beneficiaries. We examined the format of the clinical data elements, the consistency and timing of capture, and the distribution of these extracted clinical data values across conditions, hospitals, and point of hospital entry. From the results of that analysis, we identified a list of clinical data elements that were consistently captured for more than 90 percent of adults admitted for common medical conditions. In addition, only the first clinical data elements captured close to the time a patient arrived at the facility were considered in order to reflect patients' clinical status when they presented, and not the results of treatment received at the facility. Analyses showed that vital signs (heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate, temperature, and oxygen saturation) were captured within 2 hours of arrival to the hospital for most patients who were subsequently admitted to the same facility. In addition, analyses showed that weight and laboratory tests (hemoglobin, hematocrit, platelet, white blood cell (WBC) count, potassium, sodium, chloride, bicarbonate, blood urea nitrogen (BUN), creatinine, glucose, and troponin) were captured within 24 hours of arrival to the hospital for most patients who were subsequently admitted to the same facility. This was true whether patients were first assessed in the emergency department, or an inpatient unit. From these analyses, we specified the units of measurement and time window for first captured values for each of the 21 feasible and relevant core clinical data elements.

d. Core Clinical Data Elements Feasibility Testing Using Readmission and Mortality Models

In order to demonstrate that the core clinical data elements improved hospital outcome measures, we tested them in models of 30-day mortality and 30-day readmission following hospitalization from a variety of conditions. The 21 core clinical data elements shown in the table above were statistically significant predictors in at least one measure of 30-day mortality after admission for eight common

[237] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[238] 2013 Core Clinical Data Elements Technical Report Version 1.1. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

medical conditions: AMI; congestive heart failure; pneumonia; acute cerebrovascular disease; septicemia (except during labor); diabetes mellitus with complications; coronary atherosclerosis; and cardiac dysrhythmias.[239] All of the core clinical data elements listed above were also statistically significant predictors of readmission in the risk-adjusted models of 30-day readmission in a hospital-wide cohort.[240] The testing results demonstrate that the core clinical data elements enhanced the discrimination (assessed using the c-statistic) when used either in combination with or in place of administrative claims data for risk adjustment of currently reported CMS 30-day mortality and readmission outcome measures. For more detailed information on testing, we refer readers to the methodology reports posted on our Measure Methodology Web page, under the ''Downloads'' section in Core Clinical Data Elements and Hybrid Measures zip file, found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

e. Use of Core Clinical Data Elements in Hospital Quality Measures for the Hospital IQR Program

In the future, we are considering requiring hospitals to electronically submit core clinical data elements in several contexts. One use considered would be to risk-adjust claims-based hybrid quality measures similar to what is described in our discussion above. In addition, we are also considering using core clinical data elements for quality measures that apply more generally to an all-payer population (that is, a population greater than or equal to 18 years of age). As we learn more about this method of data collection, we will be able to give more information. As it stands, we envision that use of core clinical data elements for an all payer population would not be limited to merely risk-adjustment or in claims-based hybrid measures. However, should we require reporting of core clinical data elements, it would be in the context of specific measures proposed through rulemaking for the Hospital IQR Program and potentially other CMS quality programs. Specific electronically submitted core clinical data elements required would depend on the individual measure adopted.

For claims-based hybrid measures, linking variables would be required to ensure that the datasets containing administrative claims data are correctly linked with EHR datasets containing the core clinical data elements for proper risk adjustment. The linkage variables would come from an additional requirement for hospitals to submit these variables. Such linkage variables, for example, might include admission and discharge dates, CMS certification number, and date of birth. Some of these linkage variables are already routinely collected by EHRs; however, actual linkage variables required for a specific hybrid measure would depend on empirical testing of approaches to linkage for individual measure cohorts.

f. Content Exchange Standard Considerations for Core Clinical Data Elements

Data can be collected in EHRs and health information technology (IT) systems using standardized formats to promote consistent representation and interpretation, as well as to allow for systems to compute data without needing human interpretation. These standards are referred to as content exchange standards, because the standard details how data should be represented and the relationships between data elements. This allows the data to be exchanged across EHRs and health IT systems while retaining their meaning. Commonly used content exchange standards include the Consolidated Clinical Data Architecture (C–CDA) and the Quality Reporting Data Architecture (QRDA). The C–CDA standard is frequently used for the representation of summary care records and provides a format for electronically representing data within document templates and sections.[241] The QRDA standard provides a document format and standard structure to electronically report quality measure data.[242] QRDA allows for the use of CDA templates (the same underlying standard used in C–CDA) to represent quality measures using the QDM information model described above. Thus, QRDA could be considered a related standard to C–CDA for the specific quality reporting use case.

The core clinical data elements we are considering could be electronically reported to CMS formatted according to either the C–CDA or QRDA standard to promote consistent representation and more efficient calculation of hybrid measure results. These standards are also currently required for participation in the Medicare and Medicaid EHR Incentive Programs. Sections 1886(n) and 1814(l) of the Act, as added by the HITECH Act, authorize incentive payments under Medicare for eligible hospitals and critical access hospitals that successfully demonstrate the meaningful use of Certified EHR Technology (CEHRT). Section 1903(t)(6)(C) of the Act also requires that Medicaid providers adopt, implement, upgrade, or meaningfully use CEHRT if they are to receive incentives. We refer readers to the CEHRT definition adopted by the Office of the National Coordinator for Health IT (ONC) in its 2014 Edition standards and certification criteria final rule (77 FR 53972). ONC's CEHRT definition is adopted in § 170.102 and includes the capabilities defined for the Base EHR, including certification to create transitions of care documents using the C–CDA standard and to successfully report clinical quality measures using the QRDA standard (we refer readers to Table 6 of the ONC 2014 Edition standards and certification criteria final rule at 77 FR 54265).

We are specifically considering the use of QRDA Category I (QRDA I) as the transmission standard for core clinical data elements to CMS, because the core clinical data elements specified for risk adjustment need to be captured in relation to the start of an inpatient encounter, to be certain the data has been appropriately connected to the encounter. The QRDA I standard enables an individual patient-level quality report that contains quality data for one patient for one or more quality measures. For further detail on QRDA I, the most recently available QRDA I specifications can be found at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35*.

Regardless of whether C–CDA or QRDA I was used for the reporting of core clinical data elements, we note that these data exchange standards would enhance alignment across CMS programs, as well as reduce EHR developer and provider burden by adopting standards that are already in place for the exchange of electronically specified clinical and quality data.

As part of this comment solicitation, we are inviting comment on whether

[239] Hybrid 30-Day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[240] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[241] Health Level 7 International. Product Brief. Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379*.

[242] Health Level 7 International. Product Brief. Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35*.

EHR technology should be required to be certified under the ONC Health IT Certification Program [243] for the submission of the core clinical data elements for participation in the Hospital IQR Program using the most appropriate content exchange standard (such as, and not limited to, QRDA I or C–CDA). We believe that certification could test and certify that EHR technology can properly collect the core clinical data elements formatted to the appropriate content exchange standard (such as, and not limited to QRDA I or C–CDA), promoting more standardized and consistently represented data that can be submitted to CMS to risk-adjust hybrid measures.

In summary, we sought public comment on the concept of collecting core clinical data elements, and in particular, we are interested in feedback specifically regarding: (1) The use of the core clinical data elements derived from EHRs for use in risk adjustment of outcome measures as well as other types of measures; (2) the collection of additional administrative linkage variables to link a patient's episode-of-care from EHR data with his/her administrative claim data; and (3) the use of content exchange standards for reporting these data elements. Regarding the use of content exchange standards, we welcome input on the benefits and implementation considerations if CMS were to require QRDA I, as well as the tradeoffs to requiring QRDA I instead of C–CDA or other content exchange standards.

Comment: Commenters noted either outright or conditional support for the future consideration to develop hybrid measures, including the collection of additional administrative linkage variables. A few commenters noted that collection of the core clinical data elements will not impose additional burden on hospitals.

Response: We thank the commenters for their support.

Comment: Many commenters supported submitting the core clinical data elements using an EHR technology certified by the ONC. One commenter specifically supported using C–CDA. Some commenters supported using QRDA I, and others stated that they did not want CMS to use QRDA I as the content exchange standard for the core clinical data elements. Many commenters supported aligning the standards for data transmission requirements with those used in other reporting programs.

Response: We thank commenters for their suggestion to align standards across our programs. We agree that it is important to align these data collection requirements to reduce burden on hospitals and improve interoperability. We will take this feedback into consideration as we shape future proposals for the core clinical data elements.

Comment: One commenter expressed concern that hybrid measure scores may be calculated close to the end of the reporting period, which would not allow hospitals time to identify or correct discrepancies. The commenter suggested that CMS provide hospitals with timely feedback on hybrid measure results.

Response: Implementation planning for hybrid measures is ongoing and has not yet been finalized. The purpose of these measures is for comparison of hospital-level performance relative to national performance on a given outcome. These measures require a complete set of administrative claims and clinical data to reliably calculate results. The schedule for public reporting will likely be similar to the current schedule for reporting of other hospital outcome measures in the Hospital IQR Program, and would have the same lag time for data. Measures will not be calculated in real time. However, we acknowledge the importance of timely feedback and will take this into consideration.

Comment: Several commenters recommended that CMS engage stakeholders when developing hybrid measures. Several commenters requested a national provider call.

Response: We thank the commenters for their support and for encouraging stakeholder engagement during the development of hybrid measures. We note that the core clinical data elements were developed with input from a TEP and two public comment periods outside of rulemaking. Comments and responses from the latest comment period are posted on our Web site under the Download section in the ''Archived public comment files'' folder at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html.* We intend to continue to seek input from all stakeholders in the development of the hybrid measures.

Comment: Several commenters recommended that the core clinical data elements should be discussed with the MAP's Coordinating Committee and its Hospital Workgroup. Some commenters also suggested the core clinical data elements and hybrid measures should go through NQF review, or be endorsed by the NQF, prior to inclusion in a quality reporting program.

Response: As the core clinical data elements are only one piece of a quality measure, there is no formal mechanism to submit core clinical data elements independent from a measure to the MAP or for NQF endorsement. However, we will submit measures that include core clinical data elements to the MAP and NQF. We note that measures proposed in CMS quality reporting programs are included on a publicly available document entitled ''List of Measures Under Consideration'' in compliance with section 1890A(a)(2) of the Act, which are reviewed by the MAP. The Hospital 30-day Risk-standardized Acute Myocardial Infarction (AMI) Mortality eMeasure (NQF #2473), which includes five of the core clinical data elements, was reviewed by the MAP in 2013 [244] where it received conditional support pending NQF endorsement. This measure was then subsequently endorsed by the NQF in September of 2014. The Hybrid Hospital-wide 30-day Readmission measure, which includes the full core clinical data element set (with the exception of some data elements that were collinear with others), will be submitted to the NQF at the next available opportunity. The MAP encouraged further development of the Hybrid Hospital-wide 30-day Readmission measure in December 2014.[245]

Comment: Some commenters suggested that CMS enhance certification and interoperability standards before requiring hybrid measures utilizing the core clinical data elements and that these standards should be specified in the EHR Incentive Program. Several commenters recommended that CMS focus efforts toward ascertaining reliable, consistent, and valid methods of reporting electronic data, so that the reporting of the core clinical data elements as a part of hybrid measures can be implemented successfully and accurately.

Response: One of the main tenets of the 2015 Edition Standards and Certification Criteria proposed rule is interoperability and adoption of

[243] Health IT.gov. Certification Programs and Policy. Available at: *http://healthit.gov/policy-researchers-implementers/about-onc-hit-certification-program.*

[244] MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs. Available at: *https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx.*

[245] ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/.*

updated standards. We note that we have worked closely with ONC to enhance testing and validation of certified technology's ability to capture, exchange, and report electronic patient data, such as through improved testing and certification through the Cypress CQM testing and certification tool.[246] As another example, we note that ONC proposed a 2015 Edition ''CQM—report'' certification criterion in the FY 2016 IPPS/LTCH PPS proposed rule that sought stakeholder input on the standards for representing and reporting CQM data in certified health IT to improve the reliability and consistency of such data reporting (80 FR 24613 through 24614). Therefore, we thank commenters for their continued support of improving the electronic reporting process and plan to continue to make improvements as standards evolve. We thank commenters for the suggestion about including the core clinical data elements for voluntary eCQM reporting or in the EHR Incentive Program and will consider these for future rulemaking.

Comment: Several commenters recommended the continued collaboration between the ONC, the National Library of Medicine, providers, measure stewards, and electronic measure developers to improve the standardization of the terminology used to support the electronic capture of the proposed core clinical data elements. Several other commenters noted the need to ensure the alignment of the proposed data elements with data elements, definitions, and value sets used by other measures to reduce the burden on hospitals and vendors.

Response: We thank commenters for their suggestion to align the data elements across CMS, ONC (for example, the Common Clinical Data Set definition), and the healthcare industry. In an effort to ensure harmonization with other measures and reporting requirements, the core clinical data elements use existing value sets where possible. We agree that it is important to align these data collection requirements to reduce burden on hospitals and improve interoperability, and we will take this feedback into consideration as we shape future proposals for the core clinical data elements.

Comment: Several commenters suggested that CMS test the feasibility of collecting non-clinical data elements that capture patient sociodemographic status.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, as discussed in section VIII.A.7. of the preamble of this final rule, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures. To date, we have found that hospitals that care for large proportions of patients of low sociodemographic status are capable of performing well on our measures (we refer readers to the 2014 Chartbook pages 48–57, 70–73, and 78 at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*).

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research on the issue of risk adjustment for sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: Some commenters noted their concern that the quality of data extracted from electronic health records for electronic clinical quality measures are not the same as the data garnered via chart abstraction. The commenters recommended that, before CMS requires the submission of the core clinical data elements, CMS conduct further testing and analysis to ensure the accuracy and completeness of the data being submitted. One commenter suggested a testing period.

Response: For clarification, hybrid measures are not electronic clinical quality measures. Hybrid measures are administrative claims-based measures that include one use of the electronically extracted core clinical data elements, which is in the risk adjustment models of claims-based hospital-level outcome measures. We appreciate the commenter's concerns about thoroughly evaluating the core clinical data elements. Expanding on the discussion above in section VIII.A.9.c. of the preamble of this final rule, we conducted testing in 21 hospitals and found that the core clinical data elements were reliably and consistently collected for more than 90 percent of adults admitted for treatment of medical conditions.[247] We also are conducting testing of the electronic specifications of the core clinical data elements, specifically to compare the electronically exported data to chart abstracted data, at several hospitals to ensure validity of the data element codes and logic, which will be completed in 2015. Data quality and accuracy is a top concern for CMS. We will consider proposing a pilot test of data submission in future rulemaking.

Comment: One commenter was concerned that hospitals may have difficulty linking EHR data to administrative data and recommended there be stronger guidance provided around data capture and use of the core clinical data elements.

Response: Hospitals will not need to perform this linking or be responsible for calculating hybrid measure scores. Calculation of hybrid measures will require that hospitals submit some administrative data elements along with the core clinical data elements. We will then use these variables to link or merge clinical and administrative claims data for measure calculation. Such linkage variables, for example, might include admission and discharge dates, CMS certification number, and date of birth. Some of these linkage variables are already routinely collected by EHRs; however, actual linkage variables required for a specific hybrid measure would depend on empirical testing of approaches to linkage for individual measure cohorts. We do not expect submission of these data to impose a significant burden on hospitals.

Comment: Several commenters expressed concerns about the specific core clinical data elements identified, and their use. One commenter

[246] *http://projectcypress.org/.*

[247] 2013 Core Clinical Data Elements Technical Report Version 1.1. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

supported the use of hybrid measures, and requested clarification on whether or not measure developers would be able to specify other types of measures that utilize laboratory results captured after the first 24 hours, as the core clinical data elements are designed to only capture laboratory results within the 24 hours of hospital arrival. Another commenter suggested including an additional laboratory clinical data element. One commenter was concerned about capturing clinical severity.

Response: We thank the commenters for their support and their suggestions. The core clinical data elements outlined here are currently developed for the risk adjustment of hybrid measures, which are hospital-level outcomes measures. Measure developers considering using the core clinical data elements would need to evaluate each data element in the context of any new measure. Measure developers are encouraged to consider using the core clinical data elements in their measures where appropriate, recognizing that this dataset only contains first captured values. The timeframes are specified to capture the patient's condition on arrival to the hospital before care has been initiated. Capturing the first set of vital signs and laboratory results are intended to adjust for a patient's overall severity of illness upon arrival at the hospital.

We thank the commenter's suggestion to include another laboratory value. To reduce the reporting burden on hospitals, the core clinical data elements were developed as a minimum dataset that could be used across a variety of condition cohorts and measures. However, not all core clinical data elements referenced might be needed for all hybrid measures, and there may be some additional measure-specific data elements that need to be collected. For example, patients who are suspected of having had an acute myocardial infarction have a troponin test added to their blood work. Therefore, the hybrid AMI mortality measure includes four core clinical data elements, and one measure-specific core clinical data element for troponin, in the risk model. Troponin is a core clinical data element that would assist in capturing the severity of a patient's AMI. Similarly, other condition-specific data elements will be considered during development of future hybrid measures and will be included in the models if they are reliable, can be feasibly extracted, and are statistically significant in the models. We intend to continue seeking input from all stakeholders in the development of the hybrid measures.

Comment: One commenter recommended that CMS limit the core clinical data elements to only those needed for specific measures, and not impose the burden of collecting other information for potential purposes down the road that have yet to be defined. Similarly, several commenters were concerned that the volume of data collected might impact the validity and cause a submission burden. One commenter requested clarification around the use of an all-payer measure, while another commenter strongly supported hospitals reporting all of the core clinical data elements, including all-payer data.

Response: We thank the commenters for this feedback. We appreciate the commenters' concerns about the validity and submission burden for hospitals regarding the volume of data requested. We plan to propose submission of only those core clinical data elements that are used in specific hybrid quality measures. While we are considering using core clinical data elements for quality measures that apply more generally to an all-payer population, we will be able to give more information as we learn more about this method of data collection. We will take these comments into consideration as we develop future policy.

Comment: One commenter recommended that CMS develop a plan to reevaluate whether the required data elements continue to be valuable moving forward.

Response: The core clinical data elements were developed with input from ONC, the National Library of Medicine, and stakeholders from the provider and vendor communities relating to the feasibility of collection and value for quality measurement. In addition, each hybrid measure is developed to only include those variables in the risk models that contribute to improved statistical performance. We note that this was a Request For Comment in anticipation of future rulemaking, and we will develop a plan to gather input from stakeholders on whether the proposed data elements continue to retain value. We intend to formally propose any data element requirements for hospital risk-adjusted hybrid measures as part of future rulemaking in order to allow stakeholders an opportunity to comment on any proposed program requirements. We conduct annual and comprehensive reevaluation of the core clinical data elements as well as the hybrid measures according to the Blueprint for the Measures Management System. We will take this comment into consideration as we develop future policy.

Comment: One commenter recommended that CMS explore methods for obtaining patient transfer status, noting that the literature suggests that the health outcomes of patients experiencing inter-hospital transfers are different from patients receiving their entire course of care at a single institution.

Response: We thank the commenter for the suggestion. Regarding capture of transfer status as a discrete data element, we will reevaluate as advancements in electronic health record technology and interoperability may make this data element more feasible to collect in the future.

Comment: One commenter expressed concerns about obtaining historical electronic health record information from organizations that recently transitioned to a new electronic records system.

Response: We are sensitive to the potential burden on hospitals of mapping, extracting, and reporting the core clinical data elements from their EHRs. Although implementation planning is ongoing and has not yet been finalized, we are considering only prospective collection of the core clinical data elements.

We thank the commenters for their feedback and note that we will consider it in future rulemaking.

10. 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 2015 payment determination begins the first 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 year, we require that hospitals submit data on each 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 Web site at: *http://www.QualityNet.org/*. Hospitals must register and submit quality data through the secure portion of the QualityNet Web site. There are safeguards in place in accordance with the HIPAA Security Rule to protect patient information submitted through this Web site.

b. Procedural Requirements for the FY 2018 Payment Determination and Subsequent Years

The Hospital IQR Program procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to the codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811). We did not propose any changes to the procedural requirements.

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.

Comment: One commenter requested clarification on the reporting requirements for the six measures which can be reported either via chart-abstraction or electronically.

Response: Although we proposed to allow hospitals to report 6 measures (ED–1, ED–2, PC–01, STK–4, VTE–5, and VTE–6) either via chart-abstraction or electronically, we are finalizing a modified policy and these measures will remain required via chart-abstraction as previously required. However, hospitals may choose to submit electronic data, in addition to chart-abstracted data, on any of these 6 measures to meet the requirement to report 4 of 28 electronic clinical quality measures. We refer readers to section VIII.A.8.c. of the preamble of this final rule for details.

d. Alignment of the Medicare EHR Incentive Program Reporting for Eligible Hospitals and CAHs With the Hospital IQR Program

(1) Background

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) for our policies to align electronic clinical quality measures data reporting and submission periods on a calendar year basis for the FY 2017 payment determination for both the Medicare EHR Incentive Program for eligible hospitals and CAHs, and the Hospital IQR Program. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24587 through 245888), we proposed to: (1) Continue to require Certified Electronic Health Record Technology (CEHRT) 2014 Edition and (2) update reporting periods and submission deadlines, for the FY 2018 payment determination for the Hospital IQR Program.

(2) Electronic Clinical Quality Measure Certification for the FY 2018 Payment Determination

As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50251), for the Hospital IQR Program, hospitals that submit electronic clinical quality measures data for the FY 2017 payment determination are required to submit data using CEHRT 2014 Edition, which is an Electronic Health Record certification. Although we required CEHRT, eligible hospitals were not required to ensure that their CEHRT products were recertified to the most recent version of the electronic specifications for the clinical quality measures. We also stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50251), that for the FY 2017 payment determination, a hospital could submit electronic clinical quality measures for the Hospital IQR Program during CY 2015 even if they attest their aggregate measure numerators and denominators through the Medicare EHR Incentive Program. The hospital could submit as test data or production data. Test data submissions are submissions that do not count as submissions; they are practice submissions. Production data submissions are considered final submissions meant to fulfill Hospital IQR Program submission requirements.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24587), we proposed to continue the requirement for hospitals to use CEHRT 2014 Edition [248] when submitting electronic clinical quality measures for the CY 2016/FY 2018 payment determination. The Office of the National Coordinator for Health Information Technology (ONC) has proposed a new Edition of EHR technology which may be available for some providers as early as 2016 in its ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' (hereafter known as the ''2015 Edition proposed rule'') (80 FR 16804 through 16921). However, we will require hospitals to continue to submit data for Hospital IQR Program purposes using the 2014 Edition for the FY 2018 payment determination. Any changes for the Hospital IQR Program because of ONC's update will be proposed in future rule making. We invited public comments on this proposal.

Comment: A few commenters supported the proposed electronic quality measure certification requirements for the FY 2018 payment determination.

Response: We thank the commenters for their support.

Comment: One commenter supported the proposal to require that EHR technology be certified for data element submission in line with the EHR Incentive Program, and hoped that it will allow providers to further test and validate that their platforms can transmit data successfully.

Response: We thank the commenter for its support.

Comment: Several commenters requested general clarification on the CEHRT requirements for the submission of electronic clinical quality measures. Noting our proposal to require the CEHRT 2014 Edition, some commenters suggested that hospitals be able to report electronic clinical quality measures using the CEHRT 2015 Edition, if they are able, for CY 2016/FY 2018. These commenters suggested that either 2014 or 2015 CEHRT be accepted, and stated that hospitals will need ample time to adopt the CEHRT 2015 Edition in order to meet Stage 3 Meaningful Use requirements.

Response: In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24587), we proposed to continue the requirement for hospitals to use CEHRT 2014 Edition when submitting electronic clinical quality measures for the CY 2016/FY 2018 payment determination. However, in response to comments suggesting that hospitals be allowed to report using either the 2014 or 2015 edition of CEHRT, we are finalizing a modification to our proposal such that, for CY 2016/

[248] Meaningful Use in 2014. Available at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/EducationalMaterials.html.*

FY 2018 payment determination reporting of electronic clinical quality measures, hospitals can report using either the 2014 or 2015 edition of CEHRT.

Comment: One commenter asked if vendors certified to the ONC 2014 measure specifications must recertify for the May 2015 electronic clinical quality measure specifications to report electronic clinical quality measures. A few commenters specifically recommended that CMS allow hospitals to report electronic data via 2014 electronic clinical quality measure specifications, noting that some hospitals may not have the 2015 specifications available until early 2016.

Response: We require the most recent version of electronic measure specifications (the May 2015 version) for CY 2016/FY 2018 payment determination electronic reporting. We believe requiring use of the most recent electronic measure specifications is important in allowing us to collect relevant electronic data. We refer readers to section VIII.A.8.c. of the preamble of this final rule where we discuss our modified policies and note the later reporting periods (Q3 or Q4 of CY 2016) and extended submission deadline (by February 28, 2017) to provide hospitals with additional time to update to the 2015 measure specifications. The 2015 measure specifications are required whether hospitals use 2014 or 2015 CEHRT.

Comment: One commenter recommended that QRDA I data be required for the FY 2018 payment determination. One commenter expressed concern that the proposed requirement of transmitting QRDA I files is not technically feasible at present, and if implemented, as planned, in January 2016, will not leave EHR vendors or providers with sufficient time to prepare.

One commenter requested clarification on whether electronic clinical quality measures must be submitted via a QRDA I report, or if the electronic measures may be submitted via a data submission vendor. One commenter requested clarification on whether hospitals may abstract data from non-certified sources and then input these data into a certified technology for calculation and noted that organizations may have difficulty collecting all the necessary data elements required for electronic clinical quality measure reporting using their CEHRT technology.

Response: We thank the commenters for their suggestion that we require QRDA I. Although we did not specify a QRDA version requirement in the FY 2016 IPPS/LTCH PPS proposed rule, in response to comments suggesting that QRDA I be required and other comments requesting clarification on our QRDA requirement, we are finalizing a modification of our proposal to include the requirement that hospitals must report via QRDA I.

Requiring hospitals to report via QRDA I is consistent with our previous policies (described below in the preamble of this rule). It has been a requirement of 2014 Edition CEHRT under the EHR Incentive Program (we refer readers to section VIII.D.2.b. of the preamble of this final rule). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50206), we specified that hospitals that chose to voluntarily submit electronic clinical quality measures report using QRDA I. The electronic clinical quality measure validation pilot described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273) stated that participating hospitals must be able to produce QRDA Category 1 Revision 2 files extracted automatically from an EHR. Therefore, we disagree with the commenter's concern that hospitals do not have sufficient time to prepare to submit data via QRDA I.

We believe that requiring data via QRDA I is important, because: (1) It allows for patient-level validation of data rather than aggregated data; and (2) CEHRT requires data capture and reporting in QRDA I. In summary, hospitals must report data via QRDA I for 4 of 28 available eCQMs for one quarter (either CY 2016 Q3 or Q4) by the submission deadline of February 28, 2017. We believe the delayed reporting period and submission deadlines finalized will provide hospitals with adequate time to prepare to report using QRDA I.

In response to comments regarding use of a data submission vendor, hospitals may use a third party to submit QRDA I files on their behalf. Hospitals may also use abstraction or may pull the data from non-certified sources and then input these data into CEHRT for capture and reporting (QRDA I).

Comment: One commenter opposed the proposal to require hospitals to use updated specifications for eCQM reporting, and indicated that certified EHR vendors are not currently required to be updated to electronic clinical quality measure specifications and that this proposed requirement increases burden and costs. Some commenters recommended delaying updated specifications for electronic clinical quality measures until EHR vendors are required to support the annual updates. Some commenters also noted that vendors' inability to assist with technical mapping of data elements creates additional burden for hospitals. A few commenters recommended that CMS work closely with vendors to enable electronic reporting by hospitals.

Response: We thank the commenters' for their recommendations but note that we believe requiring updated measure specifications for electronic clinical quality measure reporting is appropriate in order to provide the most relevant electronic data. Further, we do not believe delaying updated specifications for electronic clinical quality measures until EHR vendors are required to support the annual updates is appropriate, because we do not have the authority to set certification requirements for vendors. However, we encourage hospitals to work closely with their vendors to ensure that a contract is in place which supports the hospital's quality reporting requirements and the annual update of those measures.

In response to concerns about a lack of vendor assistance with technical mapping, we recognize that technical mapping may be potentially burdensome and encourage hospitals to work with their vendors to overcome these issues. Further, we believe that requiring hospitals to report 4 electronic clinical quality measures for only 1 quarter (in either Q3 or Q4) of CY 2016/FY2018 payment determination, with a submission deadline of February 28, 2017, will allow more time for hospitals to overcome vendor issues, such as mapping and testing. We note that by requiring only 4 electronic clinical quality measures, we have reduced the burden of reporting by 75 percent as compared to the proposal to require 16 electronic clinical quality measures. We believe the burden associated with mapping will also be reduced by our policy to require fewer electronic clinical quality measures. In addition, we are finalizing an expansion of our Extraordinary Circumstances Extensions and Exemptions policy to include an exemption based on hardships preventing hospitals from electronically reporting. We refer readers to section VII.A.8.c. of the preamble of this final rule for a discussion of this expansion.

In response to the suggestion that we work closely with vendors to enable electronic reporting by hospitals, we currently meet with associations on a monthly basis and invite vendors to participate in Lean initiatives.[249] We

[249] eCQI Resource Center. The one-stop shop for the most current resources to support electronic clinical quality improvement. Retrieved from: *https://ecqi.healthit.gov/.*

will continue to work closely with the vendor community.

Comment: One commenter recommended adopting Release 3 of the HL7 QRDA Category I Implementation Guide (HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I) DSTU Release 3 (US Realm) or ''Release 3'').[250] [251] CMS is using QRDA Category I Release 3 for the 2015 Update electronic clinical quality measures for the 2016 reporting period, and the commenter suggested that ONC align with this version for program alignment.[252] The commenter also indicated Release 3 best incorporates known issues, fixes mistakes, and adds missing content compared to earlier versions of the QRDA Category I standard. Release 3 also uses an incremental version of the underlying data model (the Quality Data Model 4.1.1) that is a step-wise approach toward the harmonized CQM and CDS standards that the industry is currently developing. The commenter also believed that CMS and ONC should both review responses to Request for Information (RFI) on the cycle and timeline for the introduction and certification of new measures before adopting additional certifications and finalizing the frequency of testing and reporting of certification requirements.

Response: We thank the commenter for these recommendations. We believe that Release 3 of the QRDA Category I IG will ultimately improve electronic clinical quality measure processing, reduce errors, and that it better aligns with the Consolidated CDA standard Release 2.1 for interoperability, as compared to QRDA Category I Release 2 with the 2014 Errata.[253] Release 3 of the QRDA Category I IG also aligns with the forthcoming CMS 2015 update to eCQM measures for 2016 e-reporting. We refer readers to *https://ecqi.healthit.gov/ecqm* for further details on technical requirements.

We also refer readers to the HITPC recommendations (*http://healthit.gov/FACAS/sites/faca/files/HITPC_QMTF_Presentation_2015-06-3.pdf*) for additional details regarding Clinical Quality Measurement (CQM) provisions in our payment rules, including the FY 2016 IPPS/LTCH PPS final rule. Finally, we appreciate the commenter's suggestion that we review responses to the RFI with ONC before adopting certifications. We collaborate very closely with ONC in relation to certification and will continue to do so.

Comment: A few commenters asked for clarification on the frequency of required certification and, more specifically, the certification requirements for vendors as it relates to QRDA standards and the CMS Implementation Guide (whether vendors are required to certify to both the base QRDA standard and the CMS Implementation Guide). If the requirement is to certify to both, the commenters expressed concerned that this requires a duplicate effort. A few commenters recommended that CMS ensure that EHR vendors certify to one quality measurement submission format, preferably the CMS Implementation Guide. The commenters also expressed concern that certification may be required every time CMS changes its Implementation Guide to correct errors or accommodate the annual measure updates. The commenters also noted that annual recertification across multiple programs will be a significant burden on vendors as well as limit the amount of time vendors have to invest in product development initiatives and enhancement for stage 3. The commenters also recommended that CMS allow a minimum of 18 months for stakeholders to implement any major changes to quality measurements standards and also believed that recertification should not be required unless there are substantial changes to be made.

Response: We note that specific guidance on the timing for certification is provided in ONC's rule, and hospitals are encouraged to maintain updated certifications. In response to the commenter that asked about certification requirements for vendors (that is, requirements for the base QRDA standard vs. the CMS Implementation Guide [254] [255]), we note that requirements are defined by ONC. For additional certification guidelines that hospitals must use to report electronic data, we refer readers to ONC's Health IT Certification Criteria available in the eCQM library at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. In addition, *http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/QRDA_2016_CMS_IG.pdf* defines the QRDA release version. Regardless of CEHRT edition however, we are requiring use of CMS Implementation Guide for Quality Reporting Document Architecture Category I and Category III Supplementary Implementation Guide for 2016.[256]

In regard to commenter concerns about certification requirements potentially duplicating effort and limiting product development initiatives and enhancement for stage 3 and in response to suggestions that updates be limited to major changes to avoid increasing burden, we note that updating standards and requirements is necessary to reduce development efforts and ease burden associated with reporting electronic clinical quality measures.

In response to the request that 18 months be allowed for hospitals to implement standards, we are requiring hospitals to report just 4 electronic clinical quality measures for only 1 quarter (in either Q3 or Q4) of CY 2016/FY 2018 payment determination, with a submission deadline of February 28, 2017 (we refer readers to section VIII.A.8.c. of the preamble of this final rule for a further discussion of these requirements). We believe the extended submission deadline will provide more time for hospitals to update to the required specifications.

Comment: Several commenters recommended that CMS continue to work with stakeholders to improve the process for annual updates to electronic clinical quality measures, including the testing infrastructure for electronic clinical quality measures.

Response: We thank the commenters for their suggestion. We are currently engaged with stakeholders to beta test a pre-submission validation application that we anticipate making more widely available in CY 2016.

After consideration of the public comments we received, we are finalizing a modification of our proposals. Although we proposed to continue the requirement for hospitals

[250] The HL7 Implementation Guide is a document markup standard that specifies the structure and semantics of ''clinical documents'' for the purpose of exchange between healthcare providers and patients.

[251] HL7. Retrieved from: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7*.

[252] *http://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/ecqm_library.html*.

[253] Errata releases represent updates to the HL7 QRDA I standards. For more information please see: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/QRDA_EP_HQR_Guide_2015.pdf*.

[254] HL7. Retrieved from: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7*.

[255] The HL7 Implementation Guide is a document markup standard that specifies the structure and semantics of ''clinical documents'' for the purpose of exchange between healthcare providers and patients.

[256] Available in the eCQM library at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*.

to use CEHRT 2014 Edition for CY 2016 reporting/FY 2018 payment determination, we are finalizing that hospitals can report using either the 2014 or 2015 edition of CEHRT.

In addition, as discussed in this section above, we are finalizing that hospitals must submit electronic data via a QRDA Category I file.

(3) Reporting Periods and Electronic Submission Deadlines for the FY 2018 Payment Determination

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), we finalized our policy that hospitals could voluntarily submit electronic clinical quality measure data for one calendar year (CY) quarter's data for either CY Q1 (January 1–March 31, 2015), CY Q2 (April 1–June 30, 2015), or CY Q3 (July 1–September 30) by November 30, 2015.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24587 through 24588), for the FY 2018 payment determination, we proposed changes to both the reporting periods and the submission deadlines.

For the FY 2018 payment determination, we proposed that hospitals must submit both Q3 and Q4 of 2016 data for 16 measures reported as electronic clinical quality measures. We also proposed that for the FY 2018 payment determination, hospitals must submit the electronic clinical quality measure data for these two quarters (Q3 and Q4 of 2016) within 2 months after the end of the applicable calendar year quarter. For CY 2016, these deadlines would be November 30, 2016 for Q3 and February 28, 2017 for Q4. We refer readers to the table entitled ''Proposed CY 2016/FY 2018 Payment Determination Hospital IQR Program Electronic Reporting Periods and Submission Deadlines for Eligible Hospitals,'' set out in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24588).

As part of our measure maintenance process, each year we make updates to the electronic specifications of the Clinical Quality Measures approved for submission in CMS programs. These annual updates are found on the CMS Web site at: *http://www.cms.gov/Regulations-andGuidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. In developing these reporting periods and submission timelines, we considered hospitals' and vendors' ability to report electronic clinical quality measures and the burden associated with implementing the 2015 annual update. The May 2015 annual update of electronic clinical quality measure specifications will include changes to the Quality Data Model (QDM) and the Health Quality Measure Format (HQMF),[257] and we recognize that hospitals may require additional time to implement the associated software changes. Because of this, we proposed that hospitals must adopt the most recent annual update prior to data submission. For example, for the CY 2016/FY 2018 payment determination, hospitals would need to submit electronic clinical quality measure using the 2015 Annual Update. As a result and as stated above, we proposed to delay the required reporting of electronic clinical quality measures to begin with Q3 of 2016, with a reporting deadline of November 30, 2016. The table below shows the required electronic clinical quality measure reporting periods and submission deadlines for CY 2016.

CY 2016/FY 2018 PAYMENT DETERMINATION HOSPITAL IQR PROGRAM ELECTRONIC REPORTING PERIODS AND SUBMISSION DEADLINES FOR ELIGIBLE HOSPITALS

Discharge reporting periods	Submission deadline
January 1, 2016–March 31, 2016.	N/A.
April 1, 2016–June 30, 2016.	N/A.
July 1, 2016–September 30, 2016.	November 30, 2016.
October 1, 2016–December 31, 2016.	February 28, 2017.

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50319 through 50321) for a detailed discussion of the final policy in the Medicare EHR Incentive Program for eligible hospitals and CAHs as well as section VIII.D. of the preamble of this final rule where the EHR Incentive Program discusses its proposals to further align with the Hospital IQR Program.

We invited public comments on our proposal to update our electronic clinical quality measure data reporting and submission periods for the CY 2016/FY 2018 payment determination.

Comment: One commenter supported the proposed submission deadlines for electronic clinical quality measures.

Response: We thank the commenter for its support.

Comment: One commenter requested clarification on the alignment of the reporting timeframes for electronic clinical quality measures for the Hospital IQR and the EHR Incentive Programs.

Response: Consistent with our modified policies we are finalizing in section VIII.A.8.c. of the preamble of this final rule, our deadline for eCQMs in the Hospital IQR Program is February 28, 2017 for either the Q3 or Q4 reporting period. Under the EHR Incentive Program, the reporting period is one calendar quarter from Q1, Q2, or Q3 of CY 2015 and the submission deadline is 2 calendar months after the close of the reporting CY quarter. For more detail on the EHR Incentive Program, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50319 through 50321) for a detailed discussion of the final policy regarding attesting in the Medicare EHR Incentive Program for eligible hospitals and CAHs as well as section VIII.D. of the preamble of this final rule where the EHR Incentive Program discusses its proposals to further align with the Hospital IQR Program.

Comment: A few commenters suggested that the window for reporting electronic clinical quality measure data be extended from the proposed two months after the end of a quarter, to 3 or 4 months, and noted that extending the deadline will allow more time to develop reports and provide more accurate information.

Response: We recognize that commenters requested an extended submission timeline for reporting electronic data. In response to comments, we are finalizing a modification of our proposal. Instead of requiring hospitals to report 2 quarters of data (Q3 and Q4) two months following the reporting period as proposed, we will require hospitals to report the 4 electronic clinical quality measures for only 1 quarter (either Q3 or Q4) of CY 2016/FY 2018 payment determination, with a submission deadline of February 28, 2017. We also refer readers to section VIII.A.8.c. of the preamble of this rule where we discuss our modified policies. We believe that this modified submission deadline provides hospitals additional time to develop reports and provide accurate information. For example, if hospitals choose to report Q3 CY 2016 data, hospitals would have 5 months from the end of the reporting period (September 30, 2016) until the submission deadline (February 28, 2017).

Comment: Several commenters supported the options allowing simultaneous submission of electronic clinical quality measures for the Hospital IQR and EHR Incentive Programs during Q3 and Q4 of CY 2016 and noted their appreciation of CMS'

[257] eCQI Resource Center: Advance Notice of Proposed Changes for the 2015 eCQM Annual Update; Pre-release 2015 Annual Update specifications available in HQMF R2.1 format. Available at: *http://www.healthit.gov/ecqi-resource-center/*.

efforts to harmonize reporting and submission periods between the Hospital IQR Program and the EHR Incentive Program. Other commenters cited their appreciation that the number of required measures is consistent. Some commenters noted that the alignment could eventually streamline the quality measure reporting process, reduce provider reporting burdens, and support a transition towards healthcare systems focusing more on the measurement of patient-centered outcomes.

Response: We thank the commenters for their support.

Comment: Several commenters supported a long-term movement towards alignment between the Hospital IQR and the EHR Incentive Programs and urged CMS to employ a more patient-centered approach that prioritizes measures of patient outcomes that the commenter believes will reveal significant variation in performance.

Response: We thank the commenters for their support and their suggested approach. We believe that current Hospital IQR Program measures emphasize patient outcomes and we will continue to adopt new measures that do so in the future.

Comment: Several commenters noted that the Hospital IQR Program and the EHR Incentive Program are not aligned, given the proposal to require electronic reporting for the FY 2018 payment year under the Hospital IQR Program. A few commenters recommended that Meaningful Use and the Hospital IQR Programs share a single timeline for electronic reporting requirements, given that providers continue to exhibit significant challenges with electronic reporting. The commenters stated that generally, better alignment, or even outright consolidation between Meaningful-Use and Hospital IQR Program eMeasures reporting mechanisms would reduce provider burden.

Response: The Hospital IQR Program and the EHR Incentive Program were created under independent statutory authorities—section 1886(b)(3)(B)(viii) of the Act and section 1814(l)(3)(A) of the Act, respectively. The Secretary maintains the authority to determine the applicable policies under each program. We strive, to the extent possible, to align reporting periods and other policies across these programs, acknowledging that some provider burden exists with reporting for multiple programs. However, due to differences in statutes and policy goals between the programs, consolidation and exact alignment is not entirely feasible, thus, requiring the need for individual timelines for each program. However, we will continue to strive for greater alignment between the Hospital IQR and EHR Incentive Programs in future rulemaking.

Comment: One commenter requested detail on why certain ''topped-out'' measures in the Hospital IQR Program are being required by the EHR Incentive Program and asked for an explanation of the value added.

Response: We have attempted to align Hospital IQR Program measures with those in the EHR Incentive Program. Specifically, we proposed to retain the electronic versions of five measures otherwise deemed ''topped out'' (STK–06, STK–08, VTE–1, VTE–2, and VTE–3) under Hospital IQR Program standards in order to align with the EHR Incentive Program. We believe this approach allows for hospital flexibility and choice in reporting electronic clinical quality measures. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we finalized our proposal to clarify the criteria for determining when a measure is ''topped out.'' However, we continue to believe that there are circumstances in which a measure that meets criteria for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure.

Therefore, because of the continued need to balance benefits and drawbacks as well as our desire to increase transparency, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24556 through 24557), we proposed, and are finalizing in this final rule, additional factors to consider for measure removal and also include factors to consider in deciding whether to retain measures. Two of those factors are: (1) Measure aligns with other CMS programs, including other quality reporting programs, or the EHR Incentive Program; and (2) measure supports efforts to move facilities towards reporting electronic measures. We believe it is valuable and important to retain the electronic versions of these measures as hospitals learn to submit data in this form and manner.

After consideration of the public comments received, and in accordance with our modified electronic clinical quality measure reporting requirements finalized in this final rule, we are finalizing a modification of our electronic clinical quality measure reporting periods from those proposed. Specifically, we are finalizing that instead of requiring hospitals to submit both Q3 and Q4 of CY 2016 data within 2 months after the end of the applicable calendar year quarter (November 30, 2016 for Q3 and February 28, 2017 for Q4), hospitals are required to submit only one quarter (either Q3 or Q4) of CY 2016 data by February 28, 2017. We refer readers to the table below.

ADOPTED CY 2016/FY 2018 PAYMENT DETERMINATION HOSPITAL IQR PROGRAM ELECTRONIC REPORTING PERIODS AND SUBMISSION DEADLINES FOR ELIGIBLE HOSPITALS

Discharge reporting periods	Submission deadline
January 1, 2016–March 31, 2016.	N/A.
April 1, 2016–June 30, 2016.	N/A.
July 1, 2016–September 30, 2016.	February 28, 2017.
October 1, 2016–December 31, 2016.	February 28, 2017.

e. Sampling and Case Thresholds for the FY 2018 Payment Determination and Subsequent Years

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), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24588), we made one proposal regarding our population and sampling policy. However, we did not propose any changes to case thresholds.

Currently, hospitals must submit to CMS quarterly aggregate population and sample size counts for Medicare and non-Medicare discharges for all measures in the topic areas for which chart-abstracted data must be submitted. Hospitals are required to submit their aggregate population and sample size count for each topic area. In accordance with the policy we first adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), hospitals that have not treated patients in a specific topic area must still submit quarterly population and sample size counts for all Hospital IQR Program chart-abstracted data topics. For example, if a hospital has not treated AMI patients, the hospital is still required to submit a zero for its quarterly aggregate population and sample count for that topic in order to meet the requirement.

In the proposed rule, we proposed to revise this policy so that, beginning with the FY 2018 payment determination and subsequent years, hospitals will be required to submit population and sample size data only

for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program. This differs from the current policy in that there may be instances where a hospital chooses to electronically submit a measure that can be submitted either via chart-abstraction or as an electronic clinical quality measure and under the proposed policy, we would not require population and sample size data in this case. Under the proposed policy, if a hospital submits a measure as an electronic clinical quality measure, or if a measure becomes voluntary or suspended, the population and sample data would not be required.

We invited public comments on this proposal.

Comment: One commenter supported the proposed sampling and case thresholds for FY 2018 payment determination and subsequent years.

Response: We thank the commenter for its support.

After consideration of the public comment we received, we are finalizing our policy that hospitals will be required to submit population and sample size data only for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program as proposed.

We did not propose any changes to case thresholds. As stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we will continue to apply the zero denominator and case threshold exemption polices for the electronic clinical quality measures for the Hospital IQR Program. The zero denominator and case threshold exemptions are described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50323 through 50324).

f. HCAHPS Requirements for the FY 2018 Payment Determination and Subsequent Years

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 HCAHPS requirements. We did not propose any changes to HCAHPS requirements.

Hospitals and HCAHPS survey vendors should check the official HCAHPS Web site at *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight and data adjustments.

g. Data Submission Requirements for Structural Measures for the FY 2018 Payment Determination and Subsequent Years

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 did not propose any changes to data submission requirements for structural measures.

h. Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

For details on the data submission and reporting requirements for healthcare-associated infection (HAI) measures reported via the CDC's National Healthcare Safety Network (NHSN) Web site, 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), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822). Clarifications to the HAI data reporting and submission requirements policy can also be found in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24588), we did not propose any changes to data submission and reporting requirements for HAI measures reported via the NHSN.

Comment: A few commenters requested that the reporting periods for the NHSN measures be aligned across programs and noted that the HAC Program uses 2 years of data while the Hospital IQR and Hospital VBP Programs use only 1 year of data.

Response: We appreciate the commenters' feedback and suggestions. We strive, to the extent possible, to align reporting periods between our programs, acknowledging that some provider burden exists with reporting for multiple programs. However, given the varying policy, statutory, and data collections differences between these programs, exact alignment is not always feasible. For more details on the 2-year reporting period under the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717). We also refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50496) for reporting requirements for the Hospital VBP Program. As these programs grow in future years, we will examine the possibility of greater alignment.

11. Modifications to the Existing Processes for 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 and still in effect. Several modifications to these processes were finalized for the FY 2016 and FY 2017 payment determinations in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273) for the FY 2017 payment determination and subsequent years, we finalized additional modifications to these processes. These changes fall into the following categories: (a) Eligibility criteria for hospitals selected for validation; (b) number of charts to be submitted per hospital for validation; (c) combining scores for HAI and clinical process of care measures; (d) processes to submit patient medical records for chart-abstracted measures; and (e) plans to validate electronic clinical quality measure data.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273), we finalized a policy to conduct a validation pilot test for electronic clinical quality measures. We stated that we intended to complete pilot activities in CY 2015 (79 FR 50271) and that continues to be our intention. We did not propose any changes to our validation pilot test.

However, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24588 through 24589), we proposed modifications to existing processes for validation of chart-abstracted measures, specifically for the Influenza Immunization (NQF #1659) measure.

b. Modifications to the Existing Processes for Validation of Chart-Abstracted Hospital IQR Program Data

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50265 through 50273), we finalized a validation process, which included a separate validation stratum for the Influenza Immunization (NQF #1659) measure (the immunization measure validation stratum) because that measure overlapped with the

Hospital VBP Program. The finalized validation process for chart-abstracted measures included three separate validation strata: HAI, Immunization, and Other/Clinical Process of Care (79 FR 50265 through 50273). The Immunization stratum includes only one measure, Immunization for Influenza (NQF #1659). This Immunization measure was included in its own stratum because it is used in the Hospital VBP Program and we wanted to ensure that every hospital selected for validation would be validated in this topic area.

As discussed in section IV.F.2.b.(1) of the preamble of this final rule, we proposed to remove the IMM–2 Influenza Immunization measure from the Hospital VBP Program. Given the proposed removal of the Influenza Immunization measure from the Hospital VBP Program, it would be no longer necessary to ensure validation of this topic area by including a separate stratum for the Influenza measure. As a result, in the proposed rule, for the Hospital IQR Program beginning with the FY 2018 payment determination and for subsequent years, we proposed to remove the separate immunization validation stratum and include the Influenza Immunization measure in the clinical process of care measure validation stratum. Under this proposal, we would continue to apply our chart-abstracted measure validation processes only to those chart-abstracted measures that are required under the Hospital IQR Program in a chart-abstracted form (as opposed to those measures that a hospital reports as electronic clinical quality measures, for example). This proposal is consistent with our proposed policy to require population and sample size data only for those measures that are required under the Hospital IQR Program. We refer readers to section VIII.A.10.e. of the preamble of this final rule for more detail on that proposal.

Although this proposal includes an adjustment to the composition of the clinical process of care validation stratum, we did not propose any changes to the overall validation sample size. Under the existing validation process, a total of eight charts are drawn for validation—five of which are drawn from the clinical process of care measures stratum and three of which are drawn from the immunization measure stratum. Under this proposal, however, while the total number of charts drawn is the same (eight), all eight measures will be drawn from the clinical process of care measure stratum, which would then include the Influenza Immunization measure. Accordingly, one sample of charts will be drawn from the clinical process of care measures.

The proposed removal of the immunization validation stratum and inclusion of the Influenza Immunization measure in the clinical process of care validation stratum would result in an expanded pool of clinical process of care topic areas sampled for validation to include STK, VTE, ED, Sepsis, and Immunization. As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50266), all chart-abstracted measure topic areas included in the Hospital IQR Program, with the exception of the Perinatal Care topic area, are automatically included in the validation process. We do not include this topic area because the Elective Delivery PC–01 (NQF#0469) measure is reported in aggregate form, which is not consistent with our patient-level validation process (79 FR 50266).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50268 through 50269), we outlined the weighting of each of three validation topic areas: Healthcare-associated infection (66.7 percent); Immunization (22.2 percent); and Other/Clinical Process of Care (11.1 percent). The table below shows the proposed effect on topic area weighting of our proposal to remove the immunization measure validation stratum and to move the Influenza Immunization (NQF #1659) measure to the clinical process of care validation stratum.

PROPOSED TOPIC AREA WEIGHTING FOR VALIDATION FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Topic area	Weight (percent)
Healthcare-associated infection (HAI)	66.7
Other/Clinical Process of Care	33.3
Total	100.0

We invited public comments on our proposal to remove the immunization measure validation stratum, to move the Influenza Immunization (NQF #1659) measure to the clinical process of care validation stratum, and to reweight the topic areas for validation beginning with the FY 2018 payment determination and for subsequent years.

Comment: Several commenters supported the proposed removal of the separate immunization validation stratum and moving of the influenza immunization measure (IMM–2) to the clinical process of care measure validation stratum due to the removal of the measure from the Hospital VBP Program.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS continue the electronic clinical quality measure validation pilot in 2016 to ensure that a diverse group of hospitals and certified EHRs are represented and to inform an assessment of the work required to make eCQM feasible, reliable and valid. A few commenters noted their concern that the proposed data validation methodology does not address the barriers associated with reporting electronic clinical quality measures.

Response: We thank commenters for the suggestion and will consider this approach in future rulemaking. We will allow for time to evaluate results of the pilot and particularly, the effectiveness of electronically reported clinical quality measure data once the pilot concludes. If analyses prove the need for an extension of the pilot, we will consider that approach. In addition, as described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we have only heard anecdotal comments about performance level differences between the chart-abstracted and electronic modes of collection. We recognize the potential for barriers associated with electronic reporting and intend to assess for them, but at this time, we do not have sufficient data to confirm the aforementioned comments. However, once results of the validation pilot are available, we will share the results and adapt the pilot if necessary and as needed to ensure that all critical factors (such as reporting barriers) are adequately analyzed.

Comment: One commenter expressed appreciation for past education sessions clarifying the distinction between data collection methods and looked forward to seeing the results of the validation pilot.

Response: We are pleased that the commenter found value in the education sessions [258] and note that data from the electronic clinical quality measure validation pilot will be used to inform future rulemaking.

After consideration of the public comments we received, we are finalizing our proposals to remove the immunization measure validation stratum, to move the Influenza Immunization (NQF #1659) measure to the clinical process of care validation

[258] Hospital Inpatient Data Collection & CART. Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138900279093.*

stratum, and to reweight the topic areas for validation beginning with the FY 2018 payment determination and for subsequent years as proposed.

12. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for details on Data Accuracy and Completeness Acknowledgement (DACA) requirements. We did not propose any changes to the DACA requirements.

13. Public Display Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2008 IPPS 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), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site at: *http://www.medicare.gov/hospitalcompare*, but on occasion are reported on other CMS Web sites such as *http://www.cms.gov* and/or *https://data.medicare.gov*.

For the Mortality, Readmission, Complication, Payment and AHRQ measures, we will continue to replace publically reported data with a footnote for hospitals that do not have data for at least 25 cases combined during the reporting period. If there are fewer than 25 eligible cases, the measures are assigned to a separate category described as ''The number of cases is too small (fewer than 25) to reliably tell how well the hospital is performing.'' The measures are included in the calculation but are not publicly reported on *Hospital Compare.* For chart-abstracted or Web-based measures, if either the numerator or the denominator is greater than 0 and less than 11, the data are not reported on *Hospital Compare,* but rather data is displayed as ''Not Available''. This guidance does not apply to calculated measures, only to those in which cases/patients could be identified. We also provide footnote explanations on the *Hospital Compare* Web site at: *http://www.medicare.gov/hospitalcompare/Data/Footnotes.html*.

We refer readers to section VIII.A.8.b. of the preamble of this final rule, where we discuss our proposal to delay publicly reporting electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination in order to allow time for us to evaluate the effectiveness of electronically reported clinical quality measure data. In the meantime, measures reported via electronic clinical quality measures will be marked with a footnote on *Hospital Compare* noting that: (1) The hospital submitted data via EHR; (2) data are being processed and analyzed; and (3) we will eventually publicly report this data once we determine the data to be reliable and accurate.

Comment: One commenter expressed concern that patients may be confused by a lack of available data for measures that hospitals choose to report electronically, especially given that hospitals chart-abstracting a given measure will have data available. The commenter suggested that chart-abstracted data not be publicly displayed until electronic data is publicly displayed.

Response: We appreciate the commenter's concern. The decision to delay the public display of electronic measures will allow for collaboration with measure developers and vendors as needed (per suggestions by other commenters) and an in-depth evaluation of the findings from the pilot. We recognize the importance of transparency, but also want to ensure the accuracy of the information being provided. This timing will enable us to finalize policies for public display prior to the February 28, 2017 deadline for electronic clinical quality measure data submission. In regards to the chart-abstracted data not be publicly displayed until electronic data is publicly displayed, we believe that limiting the data available would not further our goals of transparency and informing the public.

Comment: One commenter requested general clarification regarding the public reporting of HAI results and requested clarification on whether the delay in publishing HAI results following the measurement period will be modified or continued.

Response: Results for HAI measures will be posted on *Hospital Compare* in accordance with our existing policy, which we are not changing. HAI measures are posted according to our current policy of reporting data from the Hospital IQR Program as soon as it is feasible. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51608) for details. Public reporting for HAI measures have not changed.

Comment: Several commenters supported the proposed public display requirements for the FY 2018 payment determination and subsequent years.

Response: We thank the commenters for their support.

Comment: Some commenters questioned the value of sharing the names of the hospitals that successfully submit electronic clinical quality measures data by the provided deadline. One commenter encouraged CMS to shift its focus to evaluate and publish the findings from the electronic clinical quality measure validation pilot. Another commenter requested clarification on what criteria and/or information will be used to establish a date for reporting on these measures going forward. Some commenters also requested additional detail on how and when electronic data will be available for public review. One commenter opposed the delay in the public display of electronic measures on *Hospital Compare,* noting that data transparency should be CMS' primary concern.

Response: We recognize the importance of transparency, but also want to ensure the accuracy of the information being provided. We refer readers to section VIII.A.8.c. of the preamble of this rule where we finalize a modified version of our proposed policy. While we proposed that measures reported via electronic clinical quality measure would be marked with a footnote on *Hospital Compare,* we are finalizing instead that any data submitted electronically will not be posted on the *Hospital Compare* Web site. We will address public reporting of electronic data in next year's rulemaking, after the conclusion and assessment of the validation pilot. Therefore, we do not have plans to share the names of hospitals submitting electronic clinical quality measures. The decision to delay the public display of electronic measures will allow for collaboration with measure developers and vendors as needed (per suggestions received from other commenters) and an in-depth evaluation of the findings from the pilot. This timing will enable us to finalize public display details prior to the February 28, 2017 deadline for electronic clinical quality measure data submission.

After consideration of the public comments we received here and in our discussion of required eCQMs in section VIII.A.8.c. of the preamble of this final rule, we are modifying our proposal to publicly report electronic clinical quality measure data submitted by hospitals for CY 2016/the FY 2018 payment determination in order to allow time for us to evaluate the effectiveness of electronically reported clinical quality measure data. Instead of

finalizing our proposal that measures reported via electronic clinical quality measures will be marked with a footnote on *Hospital Compare* noting that: (1) The hospital submitted data via EHR; (2) data are being processed and analyzed; and (3) we will eventually publicly report this data once we determine the data to be reliable and accurate, we are finalizing a policy to delay any public reporting of electronic data. We will address plans to publicly report electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination in the upcoming FY 2017 IPPS/LTCH PPS rulemaking.

14. Reconsideration and Appeal Procedures for the FY 2018 Payment Determination and Subsequent Years

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 at 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We did not propose any changes to the reconsideration and appeals procedures.

15. Hospital IQR Program Extraordinary Circumstances Extensions or Exemptions

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), and 42 CFR 412.140(c)(2) for details on the Hospital IQR Program extraordinary circumstances extensions or exemptions policy.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), we indicated that we will refer to the process as the extraordinary circumstances extensions or exemptions process and, accordingly, finalized changes reflecting this updated language in the corresponding regulation text. We did not propose any changes to the Hospital IQR Program's extraordinary circumstances extensions or exemptions policy.

Comment: A few commenters opposed mandatory reporting of electronic clinical quality data unless a hardship exception is implemented, such as is allowed for under the EHR Incentive Program, given that some hospitals will be unable to achieve the electronic reporting requirements set forth in the Hospital IQR Program. In addition, a few commenters specifically requested that we adopt a hardship exemption, similar to the one used for under the EHR Incentive Program, to consider allowing hospitals to receive an exemption from the electronic reporting requirements if a hardship is demonstrated. One commenter noted that failure to provide an exception process will unfairly expose hospitals to risk for payment penalties.

Response: We recognize that there may be special circumstances that prevent a hospital from reporting electronic clinical quality measures. In response to public comments we received and as discussed in section VIII.A.8.c. of the preamble of this final rule, we are expanding our previously established Extraordinary Circumstances Extensions/Exemptions policy (79 FR 50277) to address commenters' suggestions. We are finalizing a policy to allow hospitals to utilize the existing Extraordinary Circumstances Exemption (ECE) form to request an exemption from the Hospital IQR Program's electronic clinical quality measure reporting requirement for the applicable program year based on hardships preventing hospitals from electronically reporting. Such hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification). In addition, hospitals newly participating in the Hospital IQR Program, that are required to begin data submission under Hospital IQR Program procedural requirements at 42 CFR 412.140(c)(1), which describes submission and validation of Hospital IQR Program data, may also be considered undergoing hardship and can apply for an exemption. Lastly, we will continue to allow hospitals to apply the zero denominator and case threshold exceptions described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50323 through 50324).

This policy is based on our previously established extraordinary circumstances extensions/exemptions policy (79 FR 50277). Under the policy we are finalizing, hospitals may use the existing ECE form, which is available on QualityNet at: *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890396823&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DExtrdnryCircumForm_121714.pdf&blobcol=urldata&blobtable=MungoBlobs.*

After consideration of the public comments we received, we are expanding the Hospital IQR Program's Extraordinary Circumstances Extensions or Exemptions policy to include an exemption for hospitals that demonstrate hardship in reporting eCQMs according to the criteria discussed above. This expansion will be effective starting with the FY 2018 payment determination.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Statutory Authority

Section 3005 of the Affordable Care Act added new sections 1866(a)(1)(W) and (k) to the Act. 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 a fiscal year. 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 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561).

2. Removal of Six Surgical Care Improvement Project (SCIP) Measures From the PCHQR Program Beginning With Fourth Quarter (Q4) 2015 Discharges and for Subsequent Years

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24590), we proposed to remove six SCIP measures from the PCHQR Program beginning with fourth quarter (Q4) 2015 discharges and for subsequent years. Under this proposal, PCHs will meet reporting requirements for the FY 2016 and FY 2017 programs by submitting first quarter (Q1) through third quarter (Q3) 2015 data for these measures:

- Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis within 24 Hours Prior to Surgery to 24 Hours After Surgery (NQF #0218)
- Urinary Catheter Removed on Post-Operative Day One (POD1) or Post-Operative Day Two (POD2) with Day of Surgery Being Day Zero (formerly NQF #0453)

- Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527)
- Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528)
- Prophylactic Antibiotic Discontinued Within 24 Hours After Surgery End Time (NQF #0529)
- Surgery Patients on Beta-Blocker Therapy Prior to Admission who Received a Beta-Blocker During the Perioperative Period (NQF #0284)

We first adopted the six SCIP measures in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50840 through 50841) and refer readers to that rule for a detailed discussion of the measures. As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50205), these measures have been determined to be topped-out in the Hospital IQR Program and were removed from that program. To meet FY 2016 and FY 2017 program requirements, we proposed that PCHs would continue to submit these six measures for first quarter (Q1) 2015 through third quarter (Q3) 2015 discharges in accordance with the submission timeline we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50285). We proposed to remove these measures from the PCHQR Program because we have removed them from the Hospital IQR Program and, because they have been removed from that program, it is no longer operationally feasible to collect these measures under the PCHQR Program. By removing these measures, we also would alleviate the maintenance costs and administrative burden for PCHs associated with reporting them (79 FR 50205).

We invited public comments on these proposals.

Comment: Many commenters supported this proposal, noting the benefits of alignment with the Hospital IQR program and the reduction in burden for PCHs.

Response: We thank these commenters for their support.

Comment: Several commenters supported the intent of the proposal, but recommended that CMS also suppress public reporting on these measures because, as indicated by one commenter, one-time reporting of three quarters of the SCIP measures would promote confusion among the intended audience.

Response: We thank these commenters for their support and recommendation. Under section 1866(k)(4) of the Act, we established a procedure for making the quality data submitted under the PCHQR Program available to the public. (We refer readers to section VIII.B.6. of the preamble to this final rule for a discussion of our public display procedure.) We believe that the commenters may be concerned that a short reporting period (only 3 quarters of data) may result in the public reporting of unreliable measure rates. We understand this concern and will address criteria for data suppression from public reporting in future rulemaking.

Comment: One commenter supported the proposal to remove the SCIP measures, but recommended immediate removal, rather than waiting until the proposed 2018 program.

Response: We thank the commenter for the support and recommendation. However we believe that since PCHs have already collected a large majority of 2015 reporting period data (approximately nine months (three quarters) of data) it will present minimum burden in submitting the rest of the data by the submission deadline which is outlined in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50851 through 50852). We believe these data will provide valuable information in establishing some baselines for future measure selection surrounding this topic (surgical infection measures), especially when surgical infection rates are highly prevalent.[259]

Comment: One commenter recommended that CMS keep SCIP–VTE–2 in the PCHQR Program rather than extrapolate findings from the Hospital IQR Program.

Response: We thank the commenter for the recommendation. However, we are not extrapolating data for any of these measures from the Hospital IQR Program. Rather, we are removing the measures to improve alignment between these programs, reduce the reporting burden on PCHs, and focus our IT systems on PCHQR Program measures more closely linked with clinical outcomes.

Comment: One commenter requested that CMS clarify how removal from the Hospital IQR Program impacts the operational feasibility of SCIP–VTE–2 data in the PCHQR Program.

Response: The Hospital IQR and PCHQR Programs, among others, share the same IT infrastructure and system operation platform in collecting data. Therefore, as a result of finalizing our proposal to remove these measures from the Hospital IQR Program, we intend to remove all IT business requirements and functionalities from the IT data warehouse. This approach will allow us to free up ''space'' to allow us to include additional measures adopted for quality and incentive programs. We recognize that this approach, in this case, has a significant impact on the PCHQR Program. However, we believe that this approach is the most operationally feasible under the circumstances.

After consideration of the public comments we received, we are finalizing our proposal to remove these six SCIP measures from the PCHQR Program beginning with fourth quarter (Q4) 2015 discharges and for subsequent years.

3. New Quality Measures Beginning with the FY 2018 Program

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 have taken a number of 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 the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24590 through 24591), we did not propose any changes to the principles we consider when developing and selecting measures for the PCHQR Program.

b. Summary of New Measures

For the FY 2018 PCHQR Program, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24591 through 24593), we proposed to adopt three new quality measures. These measures meet 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).

The proposed measures are as follows:

- Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (CDC NHSN CDI Measure)
- CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) (CDC NHSN MRSA Measure)
- CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel (HCP) Measure (NQF #0431) (CDC NHSN HCP Measure)

The proposed measures were included on a publicly available

[259] CDC. Healthcare Associated Infection. Available at: *http://www.cdc.gov/HAI/surveillance/index.html.*

document entitled ''List of Measures Under Consideration (MUC) for December 1, 2014,'' [260] which is a list of quality and efficiency measures being considered for use in various Medicare programs. The proposed measures were also submitted to the Measure Applications Partnership (MAP), a public-private partnership convened by the NQF for the purpose of providing input to the Secretary on the selection of certain quality and efficiency measures. For the PCHQR Program, the MAP supported the inclusion of all three measures. The MAP's recommendations can be found in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [261]

In addition, all three of the proposed measures are currently reported under the Hospital IQR Program as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631). We refer readers to CDC's Web site for detailed measure information for these three measures.[262] [263] The sections below outline our rationale for proposing to adopt these measures.

c. CDC NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)

Healthcare-associated infections (HAIs), such as CDI and MRSA, are a significant cause of morbidity and mortality. At any given time, approximately one in every 25 inpatients has an infection related to hospital care.[264] These infections cost the U.S. health care system billions of dollars each year and lead to the loss of tens of thousands of lives. In addition, HAIs can have devastating emotional, financial and medical consequences.[265] As a result of these adverse outcomes, we are committed to increasing patient safety by partnering with hospitals (for example, the CMS Partnership for Patients) [266] to make hospital care safer, more reliable, and less costly by preventing injury and increased morbidity in patients, as well as allowing them to heal without complications.[267]

CDC reports that prolonged antibiotic exposure, a long length of stay in a health care setting, and the existence of a serious underlying illness or immunocompromised condition (for example, cancer) increase the risk of CDI.[268] As a result, we believe it is important to collect data on CDIs in the PCH setting, where cancer patients face increased exposure to these risk factors. In addition, in recent years, CDIs have become more frequent, more severe, and more difficult to treat.[269] Each year, CDI is linked to 14,000 American deaths.[270] Infection is especially common in older adults, but also affects some otherwise healthy people who are not hospitalized and/or taking antibiotics.[271]

This proposed measure addresses the National Quality Strategy (NQS) Patient Safety domain. The measure reports the standardized infection ratio (SIR) of hospital-onset CDI Laboratory-identified events (LabID events) among all patients in the facility. The numerator includes the total number of observed hospital-onset CDI LabID events among all inpatients in the facility, excluding well baby-nurseries and Neonatal Intensive Care Units.[272] The denominator includes the total number of predicted hospital-onset CDI LabID events, calculated by multiplying the number of inpatient days for the facility by the hospital-onset CDI LabID event rate for similar types of facilities (obtained from a standard population). [273] [274]

Beginning with a 2010–2011 baseline SIR of 1.0, we set a national goal to reduce the incidence of facility-onset CDI overall by 30 percent (to a SIR of 0.70) by no later than 2013. However, we were not able to meet that goal, and the rate of facility-onset CDI decreased by only 2 percent as of 2012 (to a SIR of 0.98). Therefore, we believe it is critical to continue collecting data on CDI in the hospital setting, and to adopt this measure for the PCH setting, in order to ensure the highest quality of care for cancer patients and continue our effort to support HHS' National Action Plan to Prevent Healthcare Associated Infections (HAIs) and our proposed 2020 goal to reduce facility-onset of CDI by 30 percent from the 2015 baseline.[275] The collection and evaluation of CDI data will allow PCH staff to evaluate whether their infection control efforts need improvement. We recognize the severe impact of CDI,[276] and aim to continue efforts to increase patient protection and safety, and at the same time prevent adverse infections in the PCH setting.

By proposing this measure in the PCHQR Program, we aim to continue to provide a common mechanism (that is, reporting to CDC's NHSN) that all hospitals, including PCHs, can use to uniformly submit and report measure data and inform their clinicians of the impact of targeted prevention efforts.

We invited public comments on our proposal to add the CDC NHSN CDI Outcome Measure to the PCHQR Program beginning with the FY 2018 program.

Comment: Many commenters supported inclusion of the CDC NHSN CDI Outcome Measure in the PCHQR Program specifically citing the clinical significance of this measure.

Response: We thank these commenters for their support.

Comment: One commenter did not support this measure, and stated that individuals with cancer are more susceptible to infection because they are at higher risk of being infected due to the nature of their cancer condition (that is, immunocompromised). As a result, the commenter believed PCHs should not be compared with other settings.

Response: We thank the commenter for this input. We believe that PCHs should not be compared with other settings if critical components of care, including measure population, severity

[260] Measure Applications Partnership: List of Measures Under Consideration (MUC) for December 1, 2014. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318*.

[261] National Quality Forum ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' Available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx*; and ''Spreadsheet of MAP 2015 Final Recommendations'' Available at: *http://www.qualityforum.org/map/*.

[262] CDC. Surveillance for C. difficile, MRSA, and other Drug-resistant Infections. Available at: *http://www.cdc.gov/nhsn/acute-care-hospital/cdiff-mrsa/index.html*.

[263] CDC. Surveillance for Healthcare Personnel Vaccination. Available at: *http://www.cdc.gov/nhsn/acute-care-hospital/hcp-vaccination/index.html*.

[264] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. Available at: *http://www.health.gov/hai/prevent_hai.asp#hai*.

[265] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. Available at: *http://www.health.gov/hai/prevent_hai.asp#hai*.

[266] CMS Innovation Center Partnership for Patients. Available at: *http://innovation.cms.gov/initiatives/partnership-for-patients/*.

[267] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. Available at: *http://www.health.gov/hai/prevent_hai.asp#hai*.

[268] CDC *C. difficile* FAQ. Available at: *http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_infect.html*.

[269] FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631).

[270] CDC Vital Signs. Available at: *http://www.cdc.gov/vitalsigns/pdf/2012-03-vitalsigns.pdf*.

[271] FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631).

[272] NQF QPS. Available at: *http://www.qualityforum.org/Qps/MeasureDetails.aspx?standardID=1717&print=0&entityTypeID=1*.

[273] NQF QPS. Available at: *http://www.qualityforum.org/Publications/2013/02/Patient_Safety_Measures_Complications_-_Phase_2.aspx*.

[274] FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631).

[275] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination: Proposed Targets. Available at: *http://www.health.gov/hai/pdfs/HAI-Targets.pdf*.

[276] Ibid.

of illness and vulnerability to infections, significantly differ across settings of care and cannot be reliably adjusted through risk adjustment and other statistical modeling techniques. We note that PCHQR data is displayed separate from data reported by other settings. However, CDI is extremely prevalent and highly contagious,[277] and we believe that PCH settings are as susceptible to this infectious disease as other settings where individuals with cancer or trauma (for example, burn patients) are treated. Therefore, we believe this measure could be applied to all settings and used to improve patient care. We are also fully committed to decreasing CDI rates and support the HHS' National Action Plan to Prevent Healthcare Associated Infections [278] and Healthy People 2020 initiatives.

Comment: Several commenters supported the inclusion of this measure, but recommended that CMS monitor future novel diagnostic strategies for CDI (for example, new diagnostic ways to test *Clostridium difficile* bacteria.

Response: We thank the commenters for their support. We will monitor all PCHQR Program measures closely and work with the CDC to identify future novel diagnostic strategies for CDI.

After consideration of the public comments we received, we are finalizing our proposal to add the CDC NHSN CDI Outcome Measure to the PCHQR Program beginning with the FY 2018 program.

d. CDC NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)

Invasive MRSA infections may cause approximately 18,000 deaths per year during a hospital stay.[279] Cancer patients are at increased risk for MRSA infections, specifically older adults with weakened immune systems who are receiving hospital inpatient care.[280] As a result, we believe it is important to collect data on MRSA in the PCH setting.

This proposed measure addresses the NQS Patient Safety domain. This measure reports the SIR of hospital-onset unique blood source MRSA LabID events among all inpatients in a facility. The numerator includes the total number of observed hospital-onset unique blood source MRSA LabID events among all inpatients in the facility.[281] The denominator includes the total number of predicted hospital-onset unique blood source MRSA LabID events, calculated by multiplying the number of inpatient days for the facility by the hospital-onset MRSA bacteremia LabID event rate for similar types of facilities (obtained from a standard population). [282] [283]

Beginning with a 2009 baseline SIR of 1.0, we set a national goal to reduce the incidence of facility-onset MRSA infections by 50 percent by 2020. However, by 2012 the rate of facility-onset MRSA infections decreased by only 3 percent (to a SIR of 0.97). Therefore, we believe it is critical to continue collecting data on CDI in the hospital setting, and to adopt this measure for the PCH setting, to ensure the highest quality of care for cancer patients and continue our effort to support the HHS' National Action Plan and the proposed 2020 goal to reduce facility-onset MRSA infections by 50 percent from the 2015 baseline.[284]

The collection and evaluation of MRSA data will allow PCH staff to evaluate whether their infection control efforts need improvement. By proposing this measure in the PCHQR Program, we aim to continue to provide a common mechanism (CDC NHSN) for all hospitals, including PCHs, to uniformly report measure data and inform their clinicians of the impact of targeted prevention efforts. Furthermore, we recognize the severe impact of MRSA and aim to continue our efforts to increase patient protection and safety, while at the same time preventing adverse infections in the PCH setting.

We invited public comments on our proposal to add the CDC NHSN MRSA Measure to the PCHQR Program beginning with the FY 2018 program.

Comment: Many commenters supported inclusion of the CDC NHSN MRSA Measure in the PCHQR Program specifically citing the clinical significance of this measure.

Response: We thank these commenters for their support.

Comment: Several commenters recommended postponing adoption of this measure until stratifications are adopted for cohorts of cancer patients (for example, bone marrow transplant, hematologic, and solid tumor). One commenter noted that this recommendation is consistent with recommendations from the NQF MAP Hospital Workgroup in terms of identifying benchmark calculations and risk adjustment methodologies to support valid comparisons among PCHs.

Response: We thank the commenters for their input. We would like to clarify that while the MAP Hospital Workgroup expressed concerns regarding the need for stratification of cohorts of cancer patients (BMT, Hematologic, and Solid tumor), the Coordinating Committee did not support that suggestion noting public comments received from CMS.[285] We refer readers to the NQF Web site for more public comment information.

In consultation with the CDC, we agree that the current risk models used for the calculation of MRSA bacteremia SIRs may not accurately predict these types of events in the cancer patient population, particularly within cancer hospitals. Until there are sufficient data with which to risk adjust MRSA bacteremia in this population, CDC plans to submit unadjusted, facility-specific healthcare facility-onset, incidence rates without comparison to a national benchmark. We further are clarifying that we have not provided any guidance surrounding the definition of a benchmark for any of the PCHQR Program measures.

Comment: One commenter did not support this measure and stated that individuals with cancer are more susceptible to infection because they are at higher risk of being infected due to the nature of their cancer condition (that is, immunocompromised). As a result, the commenter believed that PCHs should not be compared with other settings.

Response: We thank the commenter for this input. We believe that PCHs should not be compared with other settings if critical components of care, including measure population, severity of illness and vulnerability to infections, significantly differ across settings of care and cannot be reliably adjusted through risk adjustment and other statistical modeling techniques. We note that PCHQR data are displayed

[277] CDC. Healthcare Associated Infections (HAIs). Available at: *http://www.cdc.gov/HAI/surveillance/index.html.*

[278] HHS. National Action Plan Targets and Metrics. Available at: *http://www.health.gov/hcq/prevent_hai.asp#CDI.*

[279] Catherine Liu, Arnold Bayer, et al.: Clinical Practice Guidelines by the Infectious Disease Society of America for the Treatment of Methicillin-Resistant *Staphylococcus Aureus* Infections in Adults and Children Infectious Disease Society of America 2011; 52:e18.

[280] CDC. General Information about MRSA in Healthcare Settings: Available at: *http://www.cdc.gov/mrsa/healthcare/index.html.*

[281] NQF QPS. Available at: *http://www.qualityforum.org/Qps/MeasureDetails.aspx?standardID=1716&print=0&entityTypeID=1.*

[282] Ibid.

[283] FY 2012 IPPS/LTCH PPS final rule (76 FR 51630).

[284] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination: Proposed Targets. Available at: *http://www.health.gov/hai/pdfs/HAI-Targets.pdf.*

[285] NQF. Spreadsheet of MAP 2015 Final Recommendations. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711/.*

separately from data reported by other settings.

However, MRSA is extremely prevalent and highly contagious,[286] and we believe that PCH settings are as susceptible as other settings where individuals with cancer or trauma (for example, burn patients) are treated. Therefore, we believe this measure could be applied to all settings and used to improve patient care. We also are fully committed to decreasing MRSA rates and support the HHS' National Action Plan to Prevent Healthcare Associated Infections [287] and Healthy People 2020 initiatives.

After consideration of the public comments we received, we are finalizing our proposal to add the CDC NHSN MRSA Measure to the PCHQR Program beginning with the FY 2018 program.

e. CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel [HCP] Measure (NQF #0431) (CDC NHSN HCP Measure)

CDC estimates that in the United States, each year, on average 5 to 20 percent of the population gets influenza and more than 200,000 people are hospitalized from seasonal influenza-related complications.[288] Influenza seasons are unpredictable and can be severe. Over a period of 30 years, between 1976 and 2006, estimates of influenza-associated deaths per year in the United States ranged from a low of approximately 3,000 to a high of approximately 49,000 people.[289] Because influenza can become widespread and have serious consequences, the Advisory Committee on Immunization Practices (ACIP) recommends that all health care personnel (HCP) and persons in training for health care professions be vaccinated annually against influenza.[290] Persons who are infected with the influenza virus, including those with subclinical infection, can transmit the influenza virus to persons at higher risk for complications, such as immunocompromised cancer patients. In addition, vaccination of HCP has been associated with reduced work absenteeism and fewer deaths among patients. Results of several studies also indicate that higher vaccination coverage among HCP is associated with lower incidence of nosocomial influenza.[291] [292] [293] Such findings have led researchers to call for mandatory influenza vaccination of HCP.[294]

This proposed measure addresses the NQS Patient Safety domain. The measure reports the percent of HCP who receive the influenza vaccination.[295] The numerator includes HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year, either: (a) Received an influenza vaccination administered at the facility, or reported in writing (paper or electronic) or provided documentation that the influenza vaccination was received elsewhere; (b) were determined to have a medical contraindication or history of Guillain-Barré Syndrome within 6 weeks after a previous influenza vaccination; (c) declined the influenza vaccination; or (d) had an unknown vaccination status.[296] The denominator includes the number of HCP who are working in the health care facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact, and includes: (a) Employees; (b) licensed independent practitioners; and (c) adult students/trainees and volunteers.[297] [298] Numerators and denominators are collected separately for each of the specified groups.

We believe it is important to collect data on this measure in order to ensure the highest quality of care for cancer patients in our effort to support one of the Healthy People 2020 goals of immunizing 90 percent of health care personnel nationally by 2020.[299] Overall, final 2013–14 influenza vaccination coverage among HCP was 75.2 percent, similar to coverage of 72.0 percent in the 2012–13 season.[300] We aim to increase patient protection and safety and at the same time prevent adverse outcomes (for example, transmitting influenza to patients, specifically high risk cancer patients, and premature death due to influenza) in the PCH setting.

We believe that this measure is applicable to the PCH setting based on CDC guidelines that patients who currently have cancer or who have had certain types of cancer in the past (such as lymphoma or leukemia), are at high risk for complications from influenza, including hospitalization and death.[301] The involvement of HCP in influenza transmission has been a longstanding concern.[302] [303] Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[304]

By proposing this measure in the PCHQR Program, we aim to not only provide a common mechanism (CDC NHSN) for all hospitals, including PCHs, to uniformly report the measure data, but also to inform their clinicians of the impact of targeted prevention efforts. In addition, and most importantly, we believe that collecting this measure data in the PCH setting is necessary to support our effort to prevent unnecessary additional or prolonged hospitalizations (and associated costs), and to decrease premature death among cancer patients.

We invited public comments on our proposal to add the CDC NHSN HCP Measure to the PCHQR Program beginning with the FY 2018 program.

[286] CDC. Healthcare Associated Infections (HAIs). Available at *http://www.cdc.gov/HAI/surveillance/index.html*.

[287] HHS. National Action Plan Targets and Metrics. Available at *http://www.health.gov/hcq/prevent_hai.asp#MRSAp*.

[288] CDC. Seasonal Influenza Q&A. Available at: *http://www.cdc.gov/flu/about/qa/disease.html*.

[289] CDC. Estimating Seasonal Influenza-Associated Deaths in the United States: CDC Study Confirms Variability of Flu. Available at: *http://www.cdc.gov/flu/about/disease/us_flu-related_deaths.html*.

[290] CDC. ''Prevention and control of seasonal influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009.'' MMWR 58, no. Early Release (2009):1–52.

[291] Salgado CD, Giannetta ET, Hayden FG, Farr BM.: Preventing influenza by improving the vaccine acceptance rate of clinicians. Infection Control and Hospital Epidemiology 2004; 25: 923–928.

[292] Potter J, Stott DJ, Roberts MA, et al.: Influenza vaccination of health-care workers in long-term-care hospitals reduces the mortality of elderly patients. Journal of Infectious Diseases 1997; 175:1–6.

[293] Hayward AC, Harling R, Wetten S, et al.: Effectiveness of an influenza vaccine program for care home staff to prevent death, morbidity, and health service use among residents: cluster randomized controlled trial. British Medical Journal 2006; 333:1241–1246.

[294] Talbot TR, Bradley SF, Cosgrove SE., et al.: SHEA position paper: Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infection Control and Hospital Epidemiology 2005; 26:882–890.

[295] NQF QPS. Available at: *http://www.qualityforum.org/Qps/0431*.

[296] Ibid.

[297] Ibid.

[298] FY 2012 IPPS/LTCH PPS final rule (76 FR 51631).

[299] Healthy People 2020. Immunization and Infectious Diseases. Available at: *http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives*.

[300] CDC. Influenza Vaccination Information for Health Care Workers. Available at: *http://www.cdc.gov/flu/healthcareworkers.html*.

[301] CDC Preventing Infections in Cancer Patients. Available at: *http://www.cdc.gov/cancer/flu/*.

[302] Maltezou HC, Drancourt M.: Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91.

[303] Salgado CD, Farr BM, Hall KK, Hayden FG.: Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145–155.

[304] Wilde JA, McMillan JA, Serwint J, Butta J, O'Riordan MA, Steinhoff MC.: Effectiveness of influenza vaccine in health care professionals: a randomized trial. The Journal of the American Medical Association 1999; 281:908–913.

Comment: Many commenters supported inclusion of the CDC NHSN HCP Measure in the PCHQR Program, specifically citing the clinical significance of this measure.

Response: We thank these commenters for their support.

Comment: One commenter supported this measure, but recommended against comparing PCH measure rates to those with a different patient population when this measure is applied across programs.

Response: We thank the commenter for the comment. We believe that PCHs should not be compared with other settings if critical components of care, including measure population, severity of illness and vulnerability to infections, significantly differ across settings of care and cannot be reliably adjusted through risk adjustment and other statistical modeling techniques. We note that PCHQR data are displayed separate from data reported by other settings. However, influenza is extremely prevalent and highly contagious,[305] and we believe that PCH settings are as susceptible to this disease as other settings where individuals with cancer or trauma (for example, burn patients) are treated. Therefore, we believe this measure could be applied to all settings and used to improve patient care. We also are fully committed to decreasing influenza rates and support the HHS' National Action Plan to Prevent Healthcare Associated Infections and Healthy People 2020 initiatives.

Comment: One commenter recommended providing more specific direction for healthcare workers that decline and/or are medically excluded from influenza vaccination and have contact with patients. The commenter suggested refinement to the measure specifications to address clinical guidelines for health care workers who are excluded.

Response: For clarification purposes, the measure specification does address HCP who decline vaccination and have medical conditions that would prevent them from receiving influenza vaccine. In addition, it further defines the time from October 1 (or when the vaccine became available) through March 31 of the following year, during which HCP either: (a) Received an influenza vaccination administered at the facility, or reported in writing (paper or electronic) or provided documentation that the influenza vaccination was received elsewhere; (b) were determined to have a medical contraindication or history of Guillain-Barré Syndrome within 6 weeks after a previous influenza vaccination; (c) declined the influenza vaccination; or (d) had an unknown vaccination status.[306]

The CDC provides guidance on influenza infection control posted to their ''Infection Control in Health Care Facilities'' Web page, which is located at *http://www.cdc.gov/flu/professionals/infectioncontrol/*. These resources can be utilized for HCP with medical contraindications to influenza vaccine or decline influenza vaccination.

After consideration of the public comments we received, we are finalizing our proposal to add the CDC NHSN HCP Measure to the PCHQR Program beginning with the FY 2018 program.

In summary, we are finalizing the addition of three new measures for reporting beginning with the FY 2018 program and removing six SCIP measures beginning with Q4 2015 discharges. The PCHQR measure set will consist of 16 measures beginning with the FY 2018 program. Our policies regarding the form, manner, and timing of data collection for these measures are discussed in section VIII.B.7. of the preamble to this final rule.

The table below lists all adopted measures as well as the new measures we are finalizing for the PCHQR Program beginning with the FY 2018 program.

Topic	Summary of adopted and newly finalized PCHQR program measures beginning with the FY 2018 program
Safety and Healthcare-Associated Infection—HAI.	• CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)*. • CDC NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure (NQF #0138)*. • Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure * [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753)*. • CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)**. • CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)**. • CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel [HCP] (NQF #0431)**.
Clinical Process/Cancer-Specific Treatments.	• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223)*. • Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559)*. • Adjuvant Hormonal Therapy (NQF #0220)*.
Clinical Process/Oncology Care Measures.	• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382)*. • Oncology: Plan of Care for Pain (NQF #0383)*. • Oncology: Pain Intensity Quantified (NQF #0384)*. • Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (NQF #0390)*. • Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (NQF #0389)*.
Patient Engagement/Experience of Care.	• HCAHPS [Hospital Consumer Assessment of Healthcare Providers and Systems Survey] (NQF #0166)*.
Clinical Effectiveness Measure.	

[305] CDC. Healthcare Associated Infections (HAIs). Available at: *http://www.cdc.gov/HAI/surveillance/index.html*.

[306] NQF Quality Positioning System, Available at: *http://www.qualityforum.org/QPS/0431*.

Topic	Summary of adopted and newly finalized PCHQR program measures beginning with the FY 2018 program
	• External Beam Radiotherapy for Bone Metastases (NQF #1822)*.

*Previously finalized measures.
** Adopted beginning with the FY 2018 program in this final rule.

4. Possible New Quality Measure Topics for Future Years

Future quality measure topics and quality measure domain areas are discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50280). In addition, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24593), we welcomed public comment and specific suggestions for measure topics addressing the following CMS Quality Strategy domains: making care affordable; communication and coordination; and working with communities to promote best practices of healthy living.

Comment: Several commenters recommended that CMS give priority to developing outcome and quality-of-life measures that are most important to patients, including patient-reported outcome measures instead of process measures.

Response: We thank the commenters for their recommendation and will consider it in future years.

Comment: One commenter suggested considering the following three issues in the PCHQR Program: (1) Use of multiple data sources; (2) continuing research in areas of concern that demonstrate gaps in clinical care; and (3) efforts to develop core metrics given the variation between cancer patients (diagnoses, conditions, and priorities).

Response: We recognize and acknowledge the burden in extracting data from multiple sources (for example, administrative data and chart abstraction). However, we believe that our quality improvement effort (for example, improving quality of care and increasing life expectancy among cancer patients) outweighs the burden associated with data abstraction in selecting the most appropriate measures for the program. We will continue to engage and partner with all stakeholders in collaborating and corroborating on issues that address gaps in clinical care and developing core metrics specific to cancer treatment and care (for example, diagnoses, conditions, and priorities).

Comment: One commenter supported measure development to address cancer measurement gaps in care coordination, functional status, patient safety, patient and caregiver experience of care, population/community health, and efficiency. The commenter agreed that quality measurement strategies should be aligned with the three aims of the National Quality Strategy: better care; healthy people/healthy communities; and affordable care.

Response: We thank the commenter for this support.

Comment: Several commenters recommended that measures considered for the PCHQR Program be evaluated and risk-adjusted, prior to adoption.

Response: We thank the commenters for the recommendation. During our measure development and testing, we assess for necessity of risk-adjustment. Furthermore, measures that are not developed by CMS are also assessed for necessity of risk-adjustment when they undergo NQF endorsement and re-endorsement.

Comment: Some commenters expressed the concern that measures that are not tested in the PCH environment may result in invalid measurement due to lack of a sufficient population for statistical significance and the lack of exclusions for this complex patient population.

Response: We thank the commenters for their input. Historically, we have adopted measures across settings. Whenever feasible, we have also tested all measures for the applicable environment. We agree that a small number of cases or lack of a sufficient population could result in erroneous and misleading results. We also agree that data collection is not only necessary but crucial for quality improvement purposes. We will continue to work on ensuring that measures are appropriate, reliable, and valid for the PCH setting prior to adopting them in the PCHQR Program.

Comment: One commenter recommended that CMS consider the following three measures for the PCHQR Program: (1) Post breast conservation surgery irradiation (E0219), (2) At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer (E0225), and (3) Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection (E0221).

Response: We thank the commenter for this recommendation. These measures were submitted and reviewed by the MAP in December 2014. The MAP agreed to conditionally support these measures pending inclusion of these measures in the Hospital IQR Program for general acute care hospitals. The Workgroup also noted that these measures have extremely high levels of performance (that is, they are nearly topped out) for the PCHs.[307] Due to this reason (that they are nearly topped out in the PCH setting), we did not to propose these measures for the PCHQR Program.

Comment: One commenter recommended that CMS exercise greater caution in the future when considering additional measures for PCHQR Program to avoid the undue burden associated with requiring PCHs to develop infrastructure to report for only a short time, such as with the SCIP measures.

Response: We thank the commenter for this recommendation. We will continue to try to avoid and reduce burden in future years.

Comment: Several commenters requested that CMS outline specific guidelines for determining when measures are ''topped out'' for the PCHQR Program.

Response: We thank the commenter for this comment and will provide some guidance on topped out criteria in future rulemaking.

Comment: One commenter recommended that CMS collaborate with the PCHs in developing PCHQR Program policies in the future.

Response: We thank the commenter for this suggestion. As with all of our programs, we are fully committed to engaging and partnering with all stakeholders to ensure success and most importantly to improve quality of care.

5. 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 Web site at: *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863*.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), we described a policy under which we use a subregulatory process to make nonsubstantive updates to measures

[307] NQF. Spreadsheet of MAP 2015 Final Recommendations. Available at *http://www.qualityforum.org/map/*.

used for the PCHQR Program. We did not propose any changes to this policy in the proposed rule.

6. Public Display Requirements

a. Background

Section 1866(k)(4) of the Act requires the Secretary 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 Web site.

In order to meet these requirements, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53562 through 53563), we finalized our policy to publicly display PCHQR Program data on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) and established a preview period of 30 days prior to making such data public.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50847 through 50848), we finalized our proposal to display publicly in 2014 and subsequent years the data for two measures. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50282), we finalized our proposal to display publicly in 2015 and subsequent years the data for one measure and our proposal to display publicly no later than 2017 the data for two additional measures. In summary, we have finalized proposals to publicly display five PCHQR measures on *Hospital Compare,* including three Cancer Specific Treatment measures and two CDC NHSN HAI measures.

SUMMARY OF FINALIZED PUBLIC DISPLAY REQUIREMENTS

Measures	Public reporting
• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223).	2014 and subsequent years.
• Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559).	
• Adjuvant Hormonal Therapy (NQF #0220)	2015 and subsequent years.
• CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)	2017 and subsequent years.
• CDC NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure (NQF #0138).	

b. Additional Public Display Requirements

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24594), we proposed to publicly display six additional PCHQR measures beginning in 2016 and for subsequent years:

- Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382)
- Oncology: Plan of Care for Pain (NQF #0383)
- Oncology: Pain Intensity Quantified (NQF #0384)
- Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (NQF #0390)
- Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (NQF #0389)
- HCAHPS (NQF #0166)

We invited public comment on these proposals.

Comment: Several commenters supported the display of these measures to improve public awareness and beneficiary choice. Some of these commenters also noted the benefits of alignment across programs in publicly reporting these data.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS delay public reporting of the CDC NHSN CAUTI measure until this measure has been revised by the CDC to account for all cancer-specific risks and exclude all infections unrelated to catheter placement.

Response: We are collaborating, and will continue to collaborate, with the CDC to explore the best approach to account for all heterogeneous patient populations that are monitored and tracked using the NHSN, cancer patients being one of many such populations. As indicated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50282), we have delayed public reporting of CAUTI until no later than 2017 so that reliable baseline estimates and expected rates can be determined. We agree with the commenter and believe this delay is necessary in order to provide meaningful and reliable data available for consumers to make informed health care decisions. For more information, we refer readers to that final rule.

Comment: One commenter expressed concerns regarding how CAUTI is defined in the measure specifications because currently the measure specification does not address conditions that are critical to PCHs, such as cancer patients with multiple instruments in the genitourinary tract, urine collection obtained from different sources, long-term catheter use, cancer patients with neobladders, and cancer patients with neutropenic fever. The commenter also stated that the measure does not exclude patients with bladder fistulas between the gastrointestinal and reproductive tracts.

Response: We thank the commenter for this input. For more information about this measure, we refer readers to the CDC's measure specifications at the CDC's Web site (*http://www.cdc.gov/nhsn/acute-care-hospital/CAUTI/*).

For clarification purposes, in consultation with the CDC, we learned that the CAUTI definition working group (WG) (comprised of internal and external subject-matter experts (for example, infection preventionists, microbiologists, and hospital epidemiologists and infection disease physicians)) takes into consideration all patients (including cancer patients) when they review the NHSN CAUTI surveillance measure. While the WG agreed that these patients may be at an increased risk of Urinary Tract Infection (UTI), they also agreed that information used to identify these patients and to exclude them from surveillance is often difficult to ascertain because of shortcomings in clinical documentation of presence and timing of instrumentation.

In addition, removing these patients from CAUTI surveillance would mean omitting their UTIs and their urinary catheter days. Separating these patients and excluding their data from surveillance would be labor intensive and beyond what is logistically feasible for many, if not most, PCHs. We note that only in the case that a concomitant urine culture collected from the urethral

catheter is negative, a positive urine culture from a nephrostomy tube will be excluded from surveillance for CAUTI in the NHSN. Such a scenario would suggest that the infection was not an ascending infection of the urinary tract, that is, not from the level of the urinary catheter, but rather is occurring from another source. This exclusion is feasible for surveillance because it only requires those performing surveillance to identify nephrostomy tubes when there is an infection, rather than requiring that they identify all patients with both nephrostomy tube and urethral catheter and remove any catheter days associated with those patients from CAUTI surveillance. For further information on this measure, we refer readers to the CDC's Web site (*http://www.cdc.gov/nhsn/acute-care-hospital/CAUTI/*).

Comment: One commenter recommended that the CMS delay public reporting of the CDC NHSN CLABSI measure until this measures has been revised by the CDC to account for all cancer-specific risks and exclude all infections unrelated to central-line placement.

Response: We thank the commenter for this input. We are collaborating, and will continue to collaborate, with the CDC to explore the best approach to account for all heterogeneous patient populations that are monitored and tracked using the NHSN, cancer patients being one of many such populations. As indicated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50282), we have delayed public reporting of CLABSI until no later than 2017 so that reliable baseline estimates and expected rates can be determined. We agree with the commenter and believe this delay is necessary in order to provide meaningful and reliable data available for consumers to make informed health care decisions. For more information, we refer readers to the referenced page.

Comment: One commenter expressed specific concerns regarding how CLABSI is defined in the measure specifications because currently the measure specifications do not address conditions that are critical to PCHs. The commenter did not believe the exclusion criteria excluded cancer patients with mucosal barrier injury laboratory-confirmed bloodstream infections (MBI–LCBI) or excluded organisms that are part of the normal gastrointestinal (GI) flora, but said that cancer patients who are receiving cancer treatments (either of these combinations—chemotherapy or radiation or transplant) are at high risk of mucosal injury and highly susceptible to infection even from normal GI flora that normally are benign in healthy individuals.

Response: We thank the commenter for this input. For more information about this measure, we refer readers to the CDC's measure specifications at the CDC's Web site (*http://www.cdc.gov/nhsn/acute-care-hospital/clabsi/*).

For clarification purposes, in consultation with the CDC, we learned that the expert panel that the CDC worked with to develop the MBI–LCBI criteria developed the list of organisms which would be associated with MBI–LCBI events. This list was not intended to represent every organism that is common to the human gut, but rather to include only those which, when cultured from the bloodstream, were clinically most likely due to mucosal barrier injury rather than some other cause. Some organisms which are common to the human intestine are more commonly identified in the bloodstream due to other causes, including being associated with the presence of a central line. These organisms, for instance Pseudomonas spp., were intentionally excluded from the list for this reason. As experience with MBI–LCBI surveillance continues, the MBI–LCBI list will be reconsidered.

In addition, excluding patients from developing a CLABSI simply because they have any of the symptoms listed in the measure specification manual could result in a CLABSI measure that is tremendously insensitive. The symptoms listed are often poorly defined; variation exists in the ways that clinicians identify them and rate them. They are therefore not good candidates for inclusion in surveillance definitions and protocols. For further information on this measure, we refer readers to the CDC's Web site (*http://www.cdc.gov/nhsn/acute-care-hospital/clabsi/index.html*).

Comment: One commenter recommended that when CDC NHSN CLABSI and CDC NHSN CAUTI are publicly reported, the data be aggregated to report rates as ICU and non-ICU only versus at the inpatient unit level.

Response: We received a similar comment last year and we continue to believe our response in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50282) applies regarding this issue. We continue to collaborate with the CDC to account for all heterogeneous patient populations that are monitored and tracked using the NHSN, cancer patients being one of many such populations. We refer readers to the referenced final rule page for further discussion of this issue.

Comment: Several commenters requested that prior to requiring public reporting, CMS clarify whether the Radiation Dose Limits to Normal Tissues (NQF 0382) measure applies only to lung and pancreas cancer patients, or if breast and rectal cancer patients should be included, since this cohort expansion was submitted by the measure steward in the November 2014 for measure maintenance and update to NQF.

Response: At this time, this measure, which was finalized in FY 2014 IPPS/LTCH PPS final rule (78 FR 50842 through 50842), does not include patients with breast or rectal cancer. However, we intend to address the expanded cohort issue in next year's rulemaking to include breast and rectal cancer patients after we receive recommendations from the MAP.

Comment: One commenter requested that prior to publicly reporting, CMS clarify the sampling protocol for the Plan of Care for Pain (NQF 0383) and Pain Intensity Quantified (NQF 0384) measures because it appears that this sampling protocol may require oversampling for the Pain Intensity Quantified (NQF 0384) measure.

Response: Because these are two ''paired'' measures, cancer patients that are sampled for the Pain Intensity Quantified (NQF 0384) measure for the numerator case count are also sampled to account for the Plan of Care for Pain (NQF 0383) measure (denominator case count). This means that for any cancer patients that are reporting pain and their pain are quantified (for example, assessed for severity on a scale of one to ten), these cancer patients should have a care plan for pain management. We do not believe this approach is ''oversampling'' but rather a step toward improving quality of care by monitoring, managing, and controlling pain throughout the life cycle of cancer treatment. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50285) for further guidance on sampling these measures.

Currently, we have in place outreach and education materials (for example, tools, Webinars, among others) to assist PCHs in their data abstraction (including sampling). Information on this outreach is available on our QualityNet Web site at: (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863*). We also have established a dedicated PCHQR Help Desk hotline to assist PCHs in data abstraction (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772864236*). However, we will continue to work with our

support contractor in providing additional education materials, including Webinars, on sampling for these measures.

After consideration of the public comments we received, we are finalizing our proposal to publicly display these six additional PCHQR measures beginning in 2016 and for subsequent years. A summary of previously adopted and newly finalized public display policies is listed in the table below.

SUMMARY OF PREVIOUSLY ADOPTED AND NEWLY FINALIZED PUBLIC DISPLAY REQUIREMENTS

Measures	Public reporting
• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223).	2014 and subsequent years.
• Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559).	
• Adjuvant Hormonal Therapy (NQF #0220).	2015 and subsequent years.
• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382).	
• Oncology: Plan of Care for Pain (NQF #0383).	
• Oncology: Pain Intensity Quantified (NQF #0384).	
• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (NQF #0390).	
• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Patients (NQF #0389).	2016 and subsequent years.
• HCAHPS (NQF #0166).	
• CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).	
• CDC NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure (NQF #0138).	2017 and subsequent years.

7. Form, Manner, and Timing of Data Submission

a. Background

Section 1866(k)(2) of the Act requires that, beginning with the FY 2014 PCHQR Program, each PCH must submit to the Secretary data on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, as specified by the Secretary.

Data submission requirements and deadlines for the PCHQR Program are generally posted on the QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772864228*.

b. Reporting Requirements for New Measures: CDC NHSN CDI (NQF #1717), CDC NHSN MRSA (NQF #1716), and CDC NHSN HCP (NQF #0431) Measures

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24594 through 24595), we proposed that PCHs submit CDC NHSN CDI, MRSA, and HCP measure data for all patients to the CDC through the NHSN database. This is the same procedural/reporting mechanism used for the CDC NHSN CLABSI and CAUTI measures that we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53564) and for the CDC SSI measure that we finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848 through 50850). The data submission and reporting procedures have been set forth by the CDC for NHSN participation in general and for submission of the CDC NHSN CDI, MRSA, and HCP measures to NHSN. We refer readers to the CDC's Web site (*http://www.cdc.gov/nhsn/cms/index.html*) for detailed data submission and reporting procedures.

We proposed to adopt a quarterly submission process for the CDC NHSN CDI and MRSA measures as shown in the table below. We have successfully implemented this reporting mechanism in the Hospital IQR Program (77 FR 53539), and we strongly believe that this type of data submission is the most feasible option because PCHs are currently reporting the CDC NHSN CAUTI, CLABSI, and CDC SSI measures to the CDC NHSN this way.

PROPOSED CDC NHSN CDI (NQF #1717) AND CDC NHSN MRSA (NQF #1716) MEASURES REPORTING PERIODS AND SUBMISSION TIMEFRAMES BEGINNING WITH THE FY 2018 PROGRAM

Program year (FY)	Reporting periods (CY)	Data submission deadlines (CY)
2018	Q1 2016 events (January 1, 2016–March 31, 2016)	August 15, 2016.
	Q2 2016 events (April 1, 2016–June 30, 2016)	November 15, 2016.
	Q3 2016 events (July 1, 2016–September 30, 2016)	February 15, 2017.
	Q4 2016 events (October 1, 2016–December 31, 2016)	May 15, 2017.
Subsequent Years	Q1 events (January 1–March 31 of year 2 years before the program year).	August 15 of year two years before the program year.
	Q2 events (April 1–June 30 of year 2 years before the program year).	November 15 of year 2 years before the program year.
	Q3 events (July 1–September 30 of year 2 years before the program year).	February 15 of year 1 year before the program year.
	Q4 events (October 1–December 31 of year 2 years before the program year).	May 15 of year 1 year before the program year.

For the CDC NHSN HCP measure, we proposed that data be submitted annually by May 15 of the applicable year as shown in the table below. The vaccination period runs from October through March. The proposed reporting period for FY 2018 will include Q4 2016 and Q1 2017 counts submitted by May 15, 2017.

PROPOSED CDC NHSN HCP (NQF #0431) MEASURE REPORTING PERIODS AND SUBMISSION TIMEFRAMES BEGINNING WITH THE FY 2018 PROGRAM

Program year (FY)	Reporting periods (CY)	Data submission deadlines (CY)
2018	Q4 2016 counts (October 1, 2016–December 31, 2016). Q1 2017 counts (January 1, 2017–March 31, 2017)..	May 15, 2017.
Subsequent Years	Q4 counts (October 1–December 31 of year 2 years before the program year). Q1 counts (January 1–March 31 of year 1 year before the program year)..	May 15 of year 1 year before the program year.

We invited public comments on these proposals.

Comment: One commenter expressed support for the proposal to report the CDC NHSN MRSA and CDC NHSN CDI measures quarterly via CDC NHSN and the CDC NHSN HCP measure annually through the same process.

Response: We thank this commenter for the support.

After consideration of the public comments we received, we are finalizing our proposals for the form, manner, and timing of the CDC NHSN CDI, MRSA, and HCP measures.

As specified by CDC, the CDC NHSN CDI, MRSA, and HCP measures are reported on a facility-wide basis.[308] [309] Accordingly, we did not propose a sampling methodology for these measures because CDC requirements are to collect data on all patients or HCP in the facility. However, measures specifications could be technically updated by the measure steward (CDC). We refer readers to the CDC Web site for technical changes and/or updates (*http://www.cdc.gov/nhsn/acute-care-hospital/index.html*).

We also intend to issue guidance to PCHs that will provide additional information regarding the specific data submission deadlines that we previously finalized for certain PCHQR measures. This guidance will be issued through the QualityNet Web site.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act, requiring the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). This program applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary.

The Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. The Secretary is required to specify quality measures that are endorsed by the entity with a contract under section 1890(a) of the Act. This entity is currently the NQF. Information regarding the NQF is available at: *http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx*. The Act authorizes an exception under which the Secretary may specify non-NQF-endorsed quality measures in the case of specified areas or medical topics determined appropriate by the Secretary for which a feasible or practical measure has not been endorsed by the NQF, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286) for a detailed discussion of the history of the LTCH QRP.

In addition, section 1206(c) of the Pathway for SGR Reform Act of 2013 added section 1886(m)(5)(D)(iv) of the Act, which requires the Secretary to establish, not later than October 1, 2015, a functional status quality measure under the LTCH QRP for change in mobility among inpatients requiring ventilator support. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298 through 50301) for a detailed discussion of the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632, endorsed on 7/23/15), which we adopted in the LTCH QRP for the FY 2018 payment determination and subsequent years to meet the requirements of section 1886(m)(5)(D)(iv) of the Act.

Finally, the Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (the IMPACT Act) amended the Act in ways that affect the LTCH QRP. Specifically, section 2(a) of the IMPACT Act added section 1899B of the Act, and section 2(c)(3) of the IMPACT Act amended section 1886(m)(5) of the Act.

New section 1899B of the Act is titled Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment and Discharge Planning. Under section 1899B(a)(1) of the Act, the Secretary must require post-acute care (PAC) providers (defined in section 1899B(a)(2)(A) of the Act to include HHAs, SNFs, IRFs, and LTCHs) to submit standardized patient assessment data in accordance with section 1899B(b) of the Act, data on quality measures required under section 1899B(c)(1) of the Act, and data on resource use and other measures required under section 1899B(d)(1) of the Act. The Act also sets out specified application dates for each of the measures. The Secretary must specify the quality, resource use, and other measures not later than the applicable specified application date defined in section 1899B(a)(2)(E) of the Act.

Section 1899B(b) of the Act describes the standardized patient assessment data that PAC providers are required to submit in accordance with section 1899B(b)(1) of the Act; requires the Secretary, to the extent practicable, to match claims data with standardized patient assessment data in accordance with section 1899B(b)(2) of the Act; and requires the Secretary, as soon as practicable, to revise or replace existing patient assessment data to the extent that such data duplicate or overlap with standardized patient assessment data, in accordance with section 1899B(b)(3) of the Act.

Sections 1899B(c)(1) and (d)(1) of the Act direct the Secretary to specify

[308] CDC Multidrug–Resistant Organism & *Clostridium difficile* Infection (MDRO/CDI) Module. Available at: *http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf.*

[309] CDC HCP Vaccination Module. Available at: *http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf.*

measures that relate to at least five stated quality domains and three stated resource use and other measure domains. Section 1899B(c)(1) of the Act provides that the quality measures on which PAC providers, including LTCHs, are required to submit standardized patient assessment data and other necessary data specified by the Secretary must be with respect to at least the following domains:

- Functional status, cognitive function, and changes in function and cognitive function;
- Skin integrity and changes in skin integrity;
- Medication reconciliation;
- Incidence of major falls; and
- Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual when the individual transitions (1) from a hospital or CAH to another applicable setting, including a PAC provider or the home of the individual, or (2) from a PAC provider to another applicable setting, including a different PAC provider, hospital, CAH, or the home of the individual.

Section 1899B(c)(2)(A) of the Act provides that, to the extent possible, the Secretary must require such reporting through the use of a PAC assessment instrument and modify the instrument as necessary to enable such use.

Section 1899B(d)(1) of the Act provides that the resource use and other measures on which PAC providers, including LTCHs, are required to submit any necessary data specified by the Secretary, which may include standardized assessment data in addition to claims data, must be with respect to at least the following domains:

- Resource use measures, including total estimated Medicare spending per beneficiary;
- Discharge to community; and
- Measures to reflect all-condition risk-adjusted potentially preventable hospital readmission rates.

Sections 1899B(c) and (d) of the Act indicate that data satisfying the eight measure domains in the IMPACT Act is the minimum data reporting requirement. Therefore, the Secretary may specify additional measures and additional domains.

Section 1899B(e)(1) of the Act requires that the Secretary implement the quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act in phases consisting of measure specification, data collection, and data analysis; the provision of feedback reports to PAC providers in accordance with section 1899B(f) of the Act; and public reporting of PAC providers' performance on such measures in accordance with section 1899B(g) of the Act. Section 1899B(e)(2) of the Act generally requires that each measure specified by the Secretary under section 1899B of the Act be NQF-endorsed, but authorizes an exception under which the Secretary may select non-NQF-endorsed quality measures in the case of specified areas or medical topics determined appropriate by the Secretary for which a feasible or practical measure has not been endorsed by the NQF, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Section 1899B(e)(3) of the Act provides that the pre-rulemaking process required by section 1890A of the Act applies to quality, resource use, and other measures specified under sections 1899B(c)(1) and (d)(1) of the Act, but authorizes exceptions under which the Secretary may (1) use expedited procedures, such as ad hoc reviews, as necessary in the case of a measure required with respect to data submissions during the 1-year period before the applicable specified application date, or (2) alternatively, waive section 1890A of the Act in the case of such a measure if applying section 1890A of the Act (including through the use of expedited procedures) would result in the inability of the Secretary to satisfy any deadline specified under section 1899B of the Act with respect to the measure.

Section 1899B(f)(1) of the Act requires the Secretary to provide confidential feedback reports to PAC providers on the performance of such PAC providers with respect to quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning 1 year after the applicable specified application date.

Section 1899B(g) of the Act requires the Secretary to establish procedures for making available to the public information regarding the performance of individual PAC providers with respect to quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning not later than 2 years after the applicable specified application date. The procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act for similar purposes, that each PAC provider has the opportunity to review and submit corrections to the data and information that are to be made public with respect to the PAC provider prior to such data being made public.

Section 1899B(h) of the Act sets out requirements for removing, suspending, or adding quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act.

Section 1899B(i) of the Act requires that not later than January 1, 2016, and periodically thereafter (but not less frequently than once every 5 years), the Secretary must promulgate regulations to modify the Medicare conditions of participation (CoP) and subsequent interpretative guidance applicable to PAC providers, hospitals, and CAHs to, among other things, take into account quality, resource use, and other measures in the discharge planning process.

Section 1899B(j) of the Act requires the Secretary to allow for stakeholder input, such as through town halls, open door forums, and mailbox submissions, before the initial rulemaking process to implement section 1899B of the Act.

Section 2(c)(3) of the IMPACT Act amended section 1886(m)(5) of the Act to address the payment consequences for LTCHs with respect to the additional data which LTCHs are required to submit under section 1899B of the Act. This section added new sections 1886(m)(5)(F) and (G) to the Act and made conforming changes. New section 1886(m)(5)(F) of the Act requires LTCHs (other than a hospital classified under section 1886(d)(1)(B)(iv)(II)) of the Act) to submit the following additional data: (1) For the fiscal year beginning on the applicable specified application date and subsequent years, data on the quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act; and (2) for FY 2019 and subsequent years, the standardized patient assessment data required under section 1899B(b)(1) of the Act. Such data must be submitted in the form and manner, and at the time, specified by the Secretary. Finally, new section 1886(m)(5)(G) of the Act generally provides that to the extent that the additional data required under section 1886(m)(5)(F) of the Act duplicates other data required under section 1886(m)(5)(C) of the Act, submission of the former must be in lieu of submission of the latter.

As stated above, the IMPACT Act adds a new section 1899B to the Act that imposes new data reporting requirements for certain PAC providers, including LTCHs. Sections 1899B(c)(1) and 1899B(d)(1) of the Act collectively require that the Secretary specify quality measures and resource use and other

measures with respect to certain domains not later than the specified application date that applies to each measure domain and PAC provider setting. Section 1899B(a)(2)(E) of the Act delineates the specified application dates for each measure domain and PAC provider. The IMPACT Act also amends various other sections of the Act, including section 1886(m)(5) of the Act, to require the Secretary to reduce the otherwise applicable PPS payment to a PAC provider that does not report the new data in a form and manner, and at a time, specified by the Secretary. For LTCHs, amended section 1886(m)(5)(A)(i) of the Act requires the Secretary to reduce the payment update for any LTCH that does not satisfactorily submit the new required data.

Under the current LTCH QRP, the general timeline and sequencing of measure implementation occurs as follows: specification of measures; proposal and finalization of measures through notice-and-comment rulemaking; LTCH submission of data on the adopted measures; analysis and processing of the submitted data; notification to LTCHs regarding their quality reporting compliance with respect to a particular rate year; consideration of any reconsideration requests; and imposition of a payment reduction in a particular rate year for failure to satisfactorily submit data with respect to that rate year. Any payment reductions that are taken with respect to a rate year begin approximately one year after the end of the data submission period for that rate year and approximately two years after we first adopt the measure.

To the extent that the IMPACT Act could be interpreted to shorten this timeline so as to require us to reduce an LTCH's PPS payment for failure to satisfactorily submit data on a measure specified under section 1899B(c)(1) or (d)(1) of the Act beginning with the same rate year as the specified application date for that measure, such a timeline would not be feasible. The current timeline discussed above reflects operational and other practical constraints, including the time needed to specify and adopt valid and reliable measures, collect the data, and determine whether an LTCH has complied with our quality reporting requirements. It also takes into consideration our desire to give LTCHs enough notice of new data reporting obligations so that they are prepared to timely start reporting the data. Therefore, we intend to follow the same timing and sequence of events for measures specified under sections 1899B(c)(1) and (d)(1) of the Act that we currently follow for other measures specified under the LTCH QRP. We intend to specify each of these measures no later than the specified application dates set forth in section 1899B(a)(2)(E) of the Act and, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24597), we proposed to adopt them consistent with the requirements in the Act and Administrative Procedure Act. To the extent that we finalize a proposal to adopt a measure for the LTCH QRP that satisfies an IMPACT Act measure domain, we intend to require LTCHs to report data on the measure for the rate year that begins two years after the specified application date for that measure. Likewise, we intend to require LTCHs to begin reporting any other data specifically required under the IMPACT Act for the rate year that begins two years after we adopt requirements that would govern the submission of that data.

We received several public comments regarding the IMPACT Act, which we summarize and respond to below.

Comment: One commenter stated that its LTCH has been exempted from other CMS regulations due to unique circumstances of being located in an underserved, small community/geographic area. The commenter stated that previous exemptions have allowed their LTCH to remain open and provide critical long-term care for the patients in the community and suggested that an exemption for LTCHs with grandfathered status from the previously finalized and proposed LTCH QRP requirements described in the FY 2016 IPPS/LTCH PPS proposed rule would help ensure that critical medical care is available for patients in their communities.

Response: In the FY 2016 IPPS/LTCH PPS proposed rule, we did not propose to adopt an exception from the LTCH QRP requirements due to an LTCH being located in an underserved or small community/geographic area. Therefore, we consider this comment to be outside the scope of the proposed rule. We note that in section VIII.C.9.b. of the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24606), we proposed that a new LTCH must begin reporting quality data under the LTCH QRP by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter. If a hospital is classified as an LTCH for purposes of Medicare payments (as denoted by the last four digits of its six-digit CMS Certification Number [CCN] in the range of 2000–2299), it is subject to the requirements of the LTCH QRP. There is no statutory exemption from the LTCH QRP requirements due to an LTCH being located in an underserved or small community/geographic area, nor have we proposed any such exception in rulemaking.

Comment: Several commenters recommended that CMS develop a comprehensive plan for implementation of the IMPACT Act across all settings. The commenters stated that a comprehensive implementation plan would give PAC providers an opportunity to plan for the potential impacts to their operations and enable all stakeholders to understand CMS' approach to implementing the IMPACT Act across care settings. The commenters requested that CMS describe an overall strategy for identifying cross-cutting measures, timelines for data collection, and timelines for reporting. One commenter requested that CMS communicate its plans as soon as possible and that CMS develop setting-specific communications to facilitate understanding of the IMPACT Act requirements.

Response: We appreciate the request for a comprehensive plan to allow PAC providers to plan for the implementation of the IMPACT Act, as well as the need for stakeholder input, the development of reliable, accurate measures, clarity on the level of standardization of items and measures, and avoidance of unnecessary burden on PAC providers. Our intent has been to comply with these principles in the implementation and rollout of the QRPs in the various settings and we will continue to adhere to these principles as the agency moves forward with implementing IMPACT Act requirements.

We will use the rulemaking process to communicate timelines for implementation, including timelines for the replacement of items in PAC assessment tools, timelines for implementation of new or revised quality measures, and timelines for public reporting. As described more fully above, the IMPACT Act requires us to specify measures that relate to at least five stated quality domains and three stated resource use and other measure domains.

In addition, we must follow all processes in place for adoption of measures including the Measure Applications Partnership (MAP) and the notice and comment rulemaking process, subject to certain exceptions under section 1899B(e)(3) of the Act for expedited procedures or, alternatively, waiver of section 1890A of the Act. In our selection and specification of measures, we employ a transparent

process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. This process is based on a private-public partnership and it occurs via the MAP. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890 of the Act, to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. The NQF must convene these stakeholders and provide us with the stakeholders' input on the selection of such measures. We, in turn, must take this input into consideration in selecting such measures. In addition, the Secretary must make available to the public by December 1 of each year a list of such measures that the Secretary is considering under Title XVIII of the Act. In addition, proposed measures and specifications are to be announced through the rulemaking process in which proposed rules are published in the **Federal Register** and are available for public review and comment.

Comment: Commenters asked for more opportunities for stakeholder input into various aspects of the measure development process. The commenters requested opportunities to provide input early and ongoing input into measure development. One commenter requested opportunities for input prior to the development of proposed measure specifications. Another commenter requested that CMS establish an advisory committee of PAC providers to meet on a frequent and regular basis to help develop measure specifications.

One commenter noted that CMS did provide opportunities for input into listening sessions and open door forums. However, the commenter expressed concern that these events did not provide an opportunity for substantive input. For example, the commenter noted that the open door forum call did not provide measure specifications for public input and that the listening sessions did not include a discussion of the proposed measures. One commenter specifically noted an appreciation for the listening sessions held by CMS thus far, but also requested opportunities for more extensive collaboration.

Response: It is our intent to move forward with IMPACT Act implementation in a manner in which the measure development process continues to be transparent, and includes input and collaboration from experts, the PAC provider community, and the public at large. It is of the utmost importance to CMS to continue to engage stakeholders, including patients and their families, throughout the measure development lifecycle through their participation in our measure development public comment periods; the pre-rulemaking process; participation in the TEPs provided by our measure development contractors, as well as open door forums and other opportunities. We have already provided multiple opportunities for stakeholder input, which include the following activities: our measure development contractor(s) convened a TEP that included stakeholder experts on February 3, 2015; we convened two separate listening sessions on February 10th and March 24, 2015; we heard stakeholder input during the February 9th 2015 ad hoc MAP meeting provided for the sole purpose of reviewing the measures adopted in response to the IMPACT Act. In addition, we implemented a public mail box for the submission of comments in January 2015, *PACQualityInitiative@cms.hhs.gov*, which is listed on our post-acute care quality initiatives Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html*, and we held a Special Open Door Forum to seek input on the measures on February 25, 2015. The slides from the Special Open Door Forum are available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html*.

Comment: Several commenters requested more information regarding the timing of the development of the IMPACT Act measures, the development of associated data elements, data collection and reporting. One commenter noted the considerable time constraints under which the Secretary is required to implement the provisions of the IMPACT Act. One commenter urged CMS to first specify the standardized patient assessment data being used across all PAC settings and requested that measures be developed from standardized patient assessment data that cut across PAC assessment instruments. A few commenters requested that CMS communicate estimated implementation timelines for all data collection and reporting requirements. Some commenters urged CMS to move quickly towards changes so as to reduce burden on duplicative data collection and to allow for better cross-setting comparisons, as well as the evolution of better quality measures. However, other commenters stated that efforts had been made to move too quickly to implement IMPACT Act measures, potentially resulting in the inability to compare measures across settings. One commenter requested that CMS provide more information in the rule about the timing and sequencing of the specification of a common assessment tool, the replacement of existing data elements in the PAC assessment tool with the proposed common assessment tool, and the endorsement of quality measures. One commenter noted specifically the difficulty of the timing of specification of measures through rulemaking prior to NQF endorsement, noting that the NQF endorsement process typically resulted in changes in measure specifications.

Response: We believe that the commenter is requesting information pertaining to specific milestones related to our efforts to meet the statutory timelines which are specified within the IMPACT Act, as well as in the final rule. We intend to use the rulemaking process to establish and communicate timelines for implementation. In addition to using the rulemaking process to establish and communicate timelines for implementation, we will continue to provide ongoing education and outreach to stakeholders through Special Open Door Forums and periodic training sessions. We will also provide information about the measures at this Web site: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html.*

Because the IMPACT Act requires us to utilize the rulemaking process, prior notice of timeline and sequencing outside of the rulemaking process is not feasible. However, it should also be noted the IMPACT Act specifies a general timeline for standardization of patient assessment data. For example, the IMPACT Act specifies that LTCHs shall submit standardized patient assessment data to the Secretary for FY 2019 and for each subsequent fiscal year.

Also, as a part of the rulemaking process, we have made additional details regarding standardization of patient assessment data and the cross-setting measure specifications available at the following Web site: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*. We plan to continue

to update this information as additional measures are specified.

Comment: Several commenters expressed concerns about the reliability and accuracy of the proposed cross-setting measures. Commenters supported the use of NQF-endorsed measures, while some of the commenters expressed concern that two of the proposed measures for FY 2018 lacked NQF endorsement as proposed. A few commenters requested that CMS only use measures that had been endorsed by NQF, while one commenter strongly recommended that CMS use only NQF-endorsed measures which are specified and NQF-endorsed for the specific PAC setting in which they will be used. One commenter expressed concern that the current interpretation of the IMPACT Act could allow potential circumvention of the NQF endorsement process. Another commenter expressed concern that the due consideration process allowing CMS to select quality measures which are not NQF-endorsed is not well defined. Commenters suggested that, in the absence of NQF endorsement, to fulfill IMPACT Act requirements, CMS should implement measures that are fully supported by the MAP and a technical expert panel (TEP) that includes LTCH community input. One commenter further requested that additional consideration be given to quality measures that are proposed for implementation in the LTCH setting. The commenter stated that as the patient population in this particular setting is very different due to their medical complexity, it is of particular importance to determine whether the measure is appropriate for the LTCH setting, and if it should be modified for the LTCH setting.

Response: We intend to consider and propose appropriate measures that meet the requirements of the IMPACT Act measure domains and that have been adopted or endorsed by a consensus organization, whenever possible. However, when this is not feasible because there is no NQF-endorsed measure that meets all the requirements for a specified IMPACT Act measure domain, we intend to rely on the exception authority given to the Secretary in section 1899B(e)(2)(B)of the Act. This statutory exception, allows the Secretary to specify a measure for the LTCH QRP setting that is not NQF-endorsed where, as here, we have not been able to identify other measures on the topic that are endorsed or adopted by a consensus organization. With respect to the proposed measures for the LTCH QRP, we sought MAP review, as well as expert opinion, on the validity and reliability of those measures. Finally, we will take the variations in patient populations treated in the different type of PAC settings into consideration when selecting cross-setting measures and assessment items.

Comment: Several commenters remarked on the level of standardization among PAC settings as required by the IMPACT Act. Most commenters recognized the need to have as much standardization of measures and data collection across PAC settings as possible, while recognizing that some variations among settings may be necessary. One commenter urged CMS to work for full standardization across measures adopted for PAC settings to allow for comparison.

Another commenter asked that CMS more clearly define the subregulatory process criteria for determining what constitutes a nonsubstantive change. In addition, the commenter requested that CMS consider any potential impacts that measure numerator or denominator changes would have on the relative ranking of LTCH providers on the measure. The commenter further noted that while a change may appear to be nonsubstantive, it might adversely affect an LTCH facility ranking.

Response: We agree that standardization is important, but would like to clarify that while the IMPACT Act requires the enablement of interoperability through the use of standardized data, there will be instances where some provider types may need more or fewer standardized items than other provider types. We will work to ensure that core items are standardized.

We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates made by the NQF into the measure specifications so that the measures remain up-to-date. For example, we could use the CMS Web site as a place to announce changes. As noted in the proposed rule, the subregulatory process proposed is the same process as we have adopted for the Hospital IQR Program and which has been used successfully in that program. We believe that the criteria for what constitutes a non-substantive change could vary widely and is best described by examples, as we have done in the proposed rule. As noted, what constitutes a substantive versus a nonsubstantive change is determined on a case-by-case basis.

Comment: Commenters requested that CMS consider minimizing the burden for PAC providers when available and avoid duplication in data collection efforts. Several commenters stated the need for improved risk adjustment. One commenter requested that CMS support an additional study to develop and improve upon existing risk adjustment methods for IMPACT Act quality and resource use measures so that the newly developed methods could be used to compare outcomes across PAC settings.

Response: We appreciate the importance of avoiding undue burden and will continue to evaluate and consider any burden the IMPACT Act and the LTCH QRP places on LTCHs. In implementing the IMPACT Act thus far, we have taken into consideration the new burden that our requirements place on PAC providers, and we believe that standardizing patient assessment data will allow for the exchange of data among PAC providers in order to facilitate care coordination and improve patient outcomes.

We also will continue to assess current risk adjustment methods for IMPACT Act quality and resource use measures. As a part of measure development and maintenance, CMS supports the ongoing evaluation of risk adjustment which includes obtaining expert input, the review of relevant literature for identification of appropriate risk adjusters and appropriate testing through data analysis. We will continue these processes to promote appropriate utilization of measures in PAC settings.

Comment: One commenter requested that CMS develop a plan to revise the CoPs for hospitals to meet the IMPACT Act in an effort to align quality metrics and discharge information from inpatient settings.

Response: We recognize the necessity of a streamlined and efficient regulatory framework in order to allow the healthcare system to promote economic growth and innovation. As a part of an ongoing process, we review hospital CoPs to reduce any burden or inefficiencies imposed by actions resulting from the implementation of the IMPACT Act.

Comment: One commenter requested that CMS make data from the PAC PRD study publicly available to facilitate stakeholder analysis and input. The commenter suggested data could be made available through a research identifiable file (RIF) data request process, similar to the current process to obtain RIF data. In addition, the commenter stated the data, which would be used to develop payment recommendations, should be made available to stakeholders in a timely way.

Response: We appreciate the request for PAC PRD data to be made publicly available. Currently, we make claims and routinely collected PAC setting

assessment data available to researchers via ResDAC. We will review the feasibility of making PAC PRD data available and will ensure that data released to the public is available in a timely manner.

We thank the commenters for their views, and we will consider them as we develop quality measures and future quality measure proposals for the LTCH QRP and other PAC settings, including those that are developed and proposed in order to meet the requirements of the IMPACT Act.

2. General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the LTCH QRP

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50287) for a detailed discussion of the considerations we use for the selection of LTCH QRP quality measures. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24597), we applied the same considerations to the selection of quality, resource use, and other measures required under section 1899B of the Act for the LTCH QRP, in addition to the considerations discussed below.

The quality measures we proposed and are finalizing address some of the measure domains that the Secretary is required to specify under sections 1899B(c)(1) and (d)(1) of the Act. The totality of the measures considered to meet the requirements of the IMPACT Act will evolve, and additional measures will be proposed over time as they become available.

To meet the first specified application date applicable to LTCHs under section 1899B(a)(2)(E) of the Act, which is October 1, 2016, we have focused on measures that:

- Correspond to a measure domain in section 1899B(c)(1) or (d)(1) of the Act and are setting-agnostic: For example, falls with major injury and the incidence of pressure ulcers;
- Are currently adopted for one or more of our PAC quality reporting programs that are already either NQF-endorsed and in place or finalized for use, or already previewed by the MAP with support;
- Minimize added burden on LTCHs;
- Minimize or avoid, to the extent feasible, revisions to the existing items in assessment tools currently in use (for example, the LTCH CARE Data Set);
- Avoid, where possible, duplication of existing assessment items.

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. This process is based on a private-public partnership, and it occurs via the MAP. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890 of the Act, to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. The NQF must convene these stakeholders and provide us with the stakeholders' input on the selection of such measures. We, in turn, must take this input into consideration in selecting such measures. In addition, the Secretary must make available to the public by December 1 of each year a list of such measures that the Secretary is considering under title XVIII of the Act.

As discussed in section VIII.C.1. of the preamble of this final rule, section 1899B(e)(3) of the Act provides that the pre-rulemaking process required by section 1890A of the Act applies to the measures required under section 1899B of the Act, subject to certain exceptions for expedited procedures or, alternatively, waiver of section 1890A of the Act.

We initiated an Ad Hoc MAP process for the review of the quality measures under consideration for proposal in preparation for adoption of those quality measures into the LTCH QRP that are required by the IMPACT Act, and which must be specified by October 1, 2016. The List of Measures under Consideration (MUC List) under the IMPACT Act was made available to the public for comment during the MAP Meeting on February 9, 2015 (*http://www.meeting-support.com/downloads/703163/4524/PACLTC%20Ad%20Hoc%20Slides.pdf*). Under the IMPACT Act, these measures must be standardized so they can be applied across PAC settings and must correspond to measure domains specified in sections 1899B(c)(1) and (d)(1) of the Act. The specific cross-setting application of the measures under consideration for each such measure is discussed in the MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act: Final Report available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*. The MAP reviewed each IMPACT Act -related quality measure proposed in the proposed rule for the LTCH QRP, in light of its intended cross-setting use. We refer readers to section VIII.C.6. of the preamble of this final rule for more information on the MAP's recommendations.

As discussed in section VIII.C.1. of the preamble of this final rule, section 1899B(j) of the Act requires that we allow for stakeholder input as part of the pre-rulemaking process. To meet this requirement, we provided the following opportunities for stakeholder input: (1) Our measure development contractor convened a TEP that included stakeholder experts and patient representatives on February 3, 2015; (2) we provided two separate listening sessions on February 10, 2015 and March 5, 2015; (3) we sought public input during the February 2015 Ad Hoc MAP process provided for the sole purpose of reviewing the measures we proposed in reaction to the IMPACT Act; and (4) we sought public comment as part of our NQF measure maintenance submissions. In addition, we implemented a mailbox for the submission of comments in January 2015, *PACQualityInitiative@cms.hhs.gov*, which is accessible from our PAC quality initiatives Web site: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html*, and held a National Stakeholder Special Open Door Forum to seek input on the measures on February 25, 2015.

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for the LTCH QRP, we proposed measures that most closely align with the national priorities discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50287), and for which the MAP supports the measure concept. Further discussion as to the importance and high-priority status of these measures in the LTCH setting is included under each quality measure proposal in the preamble of this final rule. In addition, for measures not endorsed by the NQF, we have sought, to the extent practicable, to adopt measures that have been endorsed or adopted by a national consensus organization, recommended by multi-stakeholder organizations, and/or developed with the input of providers, purchasers/payers, and other stakeholders.

While we did not solicit comments specifically regarding the general considerations used for selecting quality, resource use, and other measures for the LTCH QRP, we received several comments, most notably on the NQF MAP pre-rulemaking process and MAP review process, which are addressed under the comments and responses portion of section VIII.C.1. of the preamble of this final rule.

3. Policy for Retention of LTCH QRP Measures Adopted for Previous Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615), for the LTCH QRP, we adopted a policy that once a quality measure is adopted, it will be retained for use in subsequent years, unless otherwise stated. For the purpose of streamlining the rulemaking process, when we initially adopt a measure for the LTCH QRP for a payment determination, this measure will be automatically adopted for all subsequent years or until we propose to remove, suspend, or replace the measure. For further information on how measures are considered for removal, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615).

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24598), we did not propose any changes to this policy for retaining LTCH QRP measures adopted for previous payment determinations.

4. Policy for Adopting Changes to LTCH QRP Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we finalized a policy that if the NQF updates an endorsed measure that we have adopted for the LTCH QRP in a manner that we consider to not substantively change the nature of the measure, we will use a subregulatory process to incorporate those updates to the measure specifications that apply to the LTCH QRP. Substantive changes will be proposed and finalized through rulemaking. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616) for further information on what constitutes substantive and nonsubstantive changes to a measure. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24598), we did not propose any changes to the policy for adopting changes to LTCH QRP measures.

5. Previously Adopted Quality Measures

a. Previously Adopted Quality Measures for the FY 2015 and FY 2016 Payment Determinations and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53636), for the FY 2014 payment determination and subsequent years, we adopted updated versions of National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) and the NHSN Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139). For the FY 2015 payment determination and subsequent years, we retained the application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure to the LTCH setting (initially adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51750)). We also adopted two new quality measures for the LTCH QRP for the FY 2016 payment determination and subsequent years, in addition to the three previously adopted measures (the CAUTI measure, CLABSI measure, and Pressure Ulcer measure): (1) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680); and (2) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) (77 FR 53624 through 53636).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863), we adopted the NQF-endorsed version of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure for the LTCH QRP for the FY 2015 payment determination and subsequent years.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50305), we revised the data collection and submission period for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure.

Set out below are the quality measures, both previously adopted measures retained in the LTCH QRP and measures adopted in FY 2013 and FY 2014 IPPS/LTCH PPS final rules, for the FY 2015 and FY 2016 payment determinations and subsequent years.

LTCH QRP Quality Measures Previously Adopted for the FY 2015 and FY 2016 Payment Determinations and Subsequent Years

NQF Measure ID	Measure title	Payment determination
NQF #0138	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	FY 2015 and Subsequent Fiscal Years.
NQF #0139	National Healthcare Safety Network (NHSN) Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure.	FY 2015 and Subsequent Fiscal Years.
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay).	FY 2015 and Subsequent Fiscal Years.
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).	FY 2016 and Subsequent Fiscal Years.
NQF #0431	Influenza Vaccination Coverage Among Healthcare Personnel	FY 2016 and Subsequent Fiscal Years.

b. Previously Adopted Quality Measures for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule, we adopted three additional measures—National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716), National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717), and All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) (this measure was not NQF-endorsed at the time of its initial adoption)—for the FY 2017 payment determination and subsequent years (78 FR 50863 through 50874) and one additional measure, an application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), for the FY 2018 payment determination and subsequent years (78 FR 50874 through 50877).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50305), we: (1) Revised the data collection and submission period for one measure, an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674); and (2) adopted three new quality measures—Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), Functional Status Outcome

Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632; endorsed on 7/23/15), and National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure—for the FY 2018 payment determination and subsequent years.

These measures are set out in the table below.

LTCH QRP QUALITY MEASURES PREVIOUSLY ADOPTED FOR THE FY 2017 AND FY 2018 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS

NQF Measure ID	Measure title	Payment determination
NQF #1716	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	FY 2017 and Subsequent Years.
NQF #1717	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure.	FY 2017 and Subsequent Years.
NQF #2512	All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals.	FY 2018 and Subsequent Years.
Application of NQF #0674	Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).	FY 2018 and Subsequent Years.
NQF #2631*	Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	FY 2018 and Subsequent Years.
NQF #2632*	Functional Status Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support.	FY 2018 and Subsequent Years.
Not NQF endorsed	National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.	FY 2018 and Subsequent Years.

*Endorsed on July 23, 2015. We refer readers to: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867*, NQF #2631 and NQF #2632.

6. Previously Adopted LTCH QRP Quality Measures Finalized for the FY 2018 Payment Determination and Subsequent Years

For the FY 2018 payment determination and subsequent years, in addition to the measures we are retaining under our policy described in VIII.C.3. of the preamble of this final rule, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24599 through 24605), we proposed four quality measures in order to reflect the NQF endorsement of one measure (NQF #2512) and three measures (NQF #0678; application of NQF #0674; application of NQF #2631; endorsed on 07/23/2015) to meet the requirements of the IMPACT Act. Specifically, we proposed the following measures: (a) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) to reflect NQF endorsement; (b) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) to meet the requirements of the IMPACT Act; (c) an application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) to meet the requirements of the IMPACT Act; and (d) an application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) to meet the requirements of the IMPACT Act. These quality measures are discussed in more detail below.

a. Finalized Measure To Reflect NQF Endorsement: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs (NQF #2512)

The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874). In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24600), we proposed to adopt this measure to reflect that it is NQF-endorsed for use in the LTCH setting as of December 2014. Current specifications of this NQF-endorsed measure are available for download on the NQF Web site at: *http://www.qualityforum.org/QPS/2512*.

As adopted in the FY 2014 IPPS/LTCH PPS final rule, this is a Medicare FFS claims-based measure, and LTCHs are not required to report any additional data to CMS. Because we would calculate this measure based on claims data that are already reported to the Medicare program for payment purposes, we believe there would be no additional data collection burden on LTCHs resulting from our implementation of this measure as part of the LTCH QRP. In the FY 2014 IPPS/LTCH PPS final rule, we stated that we will calculate this measure using claims data beginning with FY 2013 and FY 2014 and provide initial feedback to LTCHs prior to public reporting of this measure. However, the NQF-endorsed measure (NQF #2512) is based on 2 consecutive calendar years of Medicare FFS claims data. Therefore, in addition to our proposal to adopt the NQF-endorsed version of this measure, we proposed that the initial calculation of the measure and feedback to LTCHs, prior to public reporting of this measure, would be based on CY 2013 and CY 2014 Medicare FFS claims data related to readmissions post-LTCH discharge.

The description of this measure provided in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874) noted this measure is the ratio of the number of risk-adjusted predicted unplanned readmissions for each LTCH, including the estimated facility effect, to the average number of risk-adjusted predicted unplanned readmissions for the same patients if treated at a facility with the average effect on readmissions. This ratio is referred to as the standardized risk ratio or SRR. The NQF-endorsed specifications compute the risk-standardized readmission rate (RSRR) for this measure. The RSRR is the SRR multiplied by the overall national raw readmission rate for all LTCH stays; it is expressed as a percentage rate rather than a ratio.

This measure, which was developed to harmonize with the Hospital-Wide All-Cause Unplanned Readmission

Measure (NQF #1789) that is currently in use in the Hospital IQR Program, continues to use the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. This algorithm was refined in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50211 through 50216). The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) for the LTCH QRP will utilize the most recently updated version of the algorithm. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. The additional PAC planned readmission types specified for this measure remain the same as when first adopted through the FY 2014 IPPS/LTCH PPS final rule. Documentation on the additional PAC planned readmissions for this measure is available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2512*.

We invited public comments on: (1) Our proposal to adopt the NQF-endorsed version of All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) for the LTCH QRP and (2) our proposal that the initial feedback to LTCHs, prior to public reporting of this measure, would be based on CY 2013 and CY 2014 Medicare FFS claims data related to readmissions post-LTCH discharge.

Comment: One commenter supported the proposal to require continued reporting on this measure as part of LTCH QRP.

Response: We appreciate the commenter's support of CMS proposal of this measure as a quality measure for the LTCH QRP.

Comment: Several commenters expressed concerns over the lack of risk adjustment for sociodemographic status (SDS) factors among LTCH patients, such as community factors including access to primary care, medications, and appropriate food. One commenter recommended using proxy data on these factors such as census-derived data on income and the proportion of facilities patients that are dually eligible for Medicare and Medicaid.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding providers to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: One commenter asked whether all LTCH cases would be included in the LTCH QRP measures (including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512)) or only cases that qualify as site neutral cases.

Response: We appreciate this commenter's inquiry. At this time, all LTCH patients that meet the sample inclusion criteria for this measure are included in this All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). The inclusion criteria for this measure do not distinguish whether LTCH cases meet the site neutral qualification.

Comment: One commenter indicated that this measure was proposed to meet the requirements for the IMPACT Act and expressed concern that it does not meet all the statutory requirements, regarding quality measures, measure specifications, standardized patient assessments, and NQF endorsement.

Response: We appreciate this commenter's feedback. However, we would like to clarify that we did not propose the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) to meet the requirements of the IMPACT Act. This measure was not NQF-endorsed at the time of our initial adoption of the measure for the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874). Rather, we proposed this previously adopted measure in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24600) to reflect its NQF endorsement status.

Comment: One commenter noted that CMS had provided conflicting information on the date for the payment determination for this measure, noting that the year for the payment determination is reported as both FY 2017 and FY 2018 in the proposed rule.

Response: We appreciate this commenter's concern, and appreciate the opportunity to provide a clarification. We refer readers to our adoption of non-NQF-endorsed version of this measure for the LTCH QRP for FY 2017 payment determination in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874), related to the use of the measure as it relates to FY 2017. We note that the discrepancy in the FY 2016 IPPS/LTCH PPS proposed rule regarding the applicable FY related to the endorsed version of this measure was a technical error, and the measure is effective relative to FY 2018.

After consideration of the public comments we received, we are finalizing our proposal to adopt the NQF-endorsed version of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) for the LTCH QRP effective with the FY 2018 payment determination. We are also finalizing our proposal that the initial calculation of the measure and feedback to LTCHs, prior to public reporting of this measure, would be based on CY 2013 and CY 2014 Medicare FFS claims data related to readmissions post-LTCH discharge.

b. Finalized Measure To Address the IMPACT Act: Quality Measure Addressing the Domain of Skin Integrity and Changes in Skin Integrity: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)

Section 1899B(c)(1) of the Act directs the Secretary to specify quality measures on which PAC providers are required under the applicable reporting provisions to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is skin integrity and changes in skin integrity. The

specified application date by which the Secretary must specify quality measures to address this domain for IRFs, SNFs, and LTCHs is October 1, 2016, and for HHAs is January 1, 2017. To satisfy these requirements, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24600 through 24601), we proposed to adopt the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure, that we have already adopted for the LTCH QRP, as a cross-setting quality measure that satisfies the domain of skin integrity and changes in skin integrity. The reporting of data for this measure would affect the FY 2018 payment determination and subsequent years. In the LTCH setting, the measure assesses the percent of patients with Stage 2 through Stage 4 pressure ulcers that are new or worsened since admission.

As described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51754 through 51756), pressure ulcers are high-cost adverse events and are an important measure of quality. For information on the detailed rationale for relevance, evidence, appropriateness, importance, and applicability of this quality measure in the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51754 through 51756) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863). Measure specifications are available on the NQF Web site at: *http://www.qualityforum.org/QPS/0678*.

The IMPACT Act requires the implementation of quality measures and resource use and other measures that are standardized and interoperable across PAC settings as well as the reporting of standardized patient assessment data and other necessary data specified by the Secretary. This requirement is in line with the NQF Steering Committee report, which stated, ''to understand the impact of pressure ulcers across settings, quality measures addressing prevention, incidence, and prevalence of pressure ulcers must be harmonized and aligned.'' [310] The Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure is NQF-endorsed and has been successfully implemented using a harmonized set of data elements in three PAC settings (LTCHs, IRFs, and SNFs). As discussed in section VIII.C.6.b. of the preamble of this final rule, above, an application of this measure was adopted for the LTCH QRP in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51753 through 51756) for the FY 2014 payment determination, and the current NQF-endorsed version of the measure was adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863) for the FY 2015 payment determination and subsequent years. The measure has been in use in the LTCH QRP since October 1, 2012, and LTCHs are currently submitting data for this measure using the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set.

The Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure was adopted for use in the IRF QRP in the FY 2012 IRF PPS final rule (76 FR 47876 through 47878) for the FY 2014 payment determination and subsequent years and has been successfully submitted by IRFs using the Inpatient Rehabilitation Facility—Patient Assessment Instrument (IRF–PAI) since October 2012. It has also been implemented in the CMS Nursing Home Quality Initiative, using the Minimum Data Set (MDS) Version 3.0 since 2011, and is currently publicly reported on CMS' *Nursing Home Compare* at: *http://www.medicare.gov/nursinghomecompare/search.html*.

A TEP convened by our measure development contractor in February 2015, provided input on the technical specifications of this quality measure, as well as the applicability of this measure as a cross-setting measure across PAC settings, including the LTCH setting, to meet the requirements of the IMPACT Act. The TEP supported the applicability of this measure as a cross-setting measure across PAC settings and also supported our efforts to standardize items for data collection and submission of this measure as well as our efforts to standardize the measure for cross-setting development. In addition, on February 9, 2015, the MAP met to provide input to CMS on the measure. The MAP supported the use of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure in the LTCH QRP as a cross-setting quality measure. More information about the MAP's recommendations for this measure is included in: The MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act: Final Report which is available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

We proposed that data collection for this measure continue to occur through the LTCH CARE Data Set submitted through the CMS Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system. LTCHs have been submitting data on the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure through the LTCH CARE Data Set since October 2012. By building on the existing reporting and submission infrastructure for LTCHs, we intend to minimize the administrative burden related to data collection and submission for this measure under the LTCH QRP. For more information on LTCH QRP reporting using the QIES ASAP system, we refer readers to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

We proposed that data collected using standardized items through the LTCH CARE Data Set would continue to be used to calculate this quality measure. LTCH CARE Data Set items used to identify new or worsened pressure ulcers consist of: M0800A [311] (Worsening in Pressure Ulcer Status Since Prior Assessment, Stage 2); M0800B [312] (Worsening in Pressure Ulcer Status Since Prior Assessment, Stage 3); and M0800C [313] (Worsening in Pressure Ulcer Status Since Prior Assessment, Stage 4). In addition, we proposed to continue to use items from the LTCH CARE Data Set to risk-adjust this quality measure. These items consist of: GG0160C [314] (Functional Mobility; Lying to Sitting on Side of Bed), H0400 (Bowel Continence); I0900 (Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD); I2900 (Diabetes Mellitus), K0200A (Height); and K0200B (Weight). More information about the LTCH CARE Data Set items is available in the LTCH QRP Manual available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-*

[310] National Quality Forum. National voluntary consensus standards for developing a framework for measuring quality for prevention and management of pressure ulcers. April 2008. Available at: *http://www.qualityforum.org/Projects/Pressure_Ulcers.aspx*.

[311] For the April 1, 2016 release of the LTCH CARE Data Set version 3.00, item M0800A will be revised to Worsening in Pressure Ulcer Status Since Admission, Stage 2.

[312] For the April 1, 2016 release of the LTCH CARE Data Set version 3.00, item M0800B will be revised to Worsening in Pressure Ulcer Status Since Admission, Stage 3.

[313] For the April 1, 2016 release of the LTCH CARE Data Set version 3.00, item M0800C will be revised to Worsening in Pressure Ulcer Status Since Admission, Stage 4.

[314] For the April 1, 2016 release of LTCH CARE Data Set version 3.00, this item (GG0160C) will be renumbered to GG0170C.

Assessment-Instruments/LTCH-Quality-Reporting/index.html.

The specifications and data elements for the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure for LTCHs are available in the LTCH QRP Manual at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

We invited public comment on our proposal to adopt the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure for the FY 2018 payment determination and subsequent years to fulfill the requirements of the IMPACT Act.

Comment: Several commenters supported the proposal to implement the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) to fulfill the requirements of the IMPACT Act. Commenters noted that this measure is NQF-endorsed for the LTCH setting, data have been collected by LTCHs as part of the LTCH QRP since October 2012, and the NQF MAP supported the use of this measure in the LTCH QRP to meet the requirements of the IMPACT Act.

Response: We thank these commenters for their support of our proposal.

Comment: One commenter supported the proposal to implement this measure to fulfill the requirements of the IMPACT Act and stated that the implementation of this measure would not add any additional burden for LTCHs, because there are already mechanisms in place to collect and submit the pressure ulcer data. The commenter sought clarification regarding the coding instructions for the new or worsened unstageable pressure ulcer items added to Section M of the LTCH CARE Data Set version 3.00.

Response: We thank the commenter for its support of our proposal and recognition that the implementation of this measure does not add additional data collection and reporting burden for LTCHs. Regarding the commenter's request related to coding the LTCH CARE Data Set version 3.00 new items, we are committed to providing additional guidance to support and allow LTCHs to accurately interpret and complete quality reporting items, including the new or worsened unstageable pressure ulcer items included in Section M of the LTCH CARE Data Set version 3.00. Similar to training and outreach efforts that we have conducted in the past, we will make available an updated LTCH QRP Manual Version 3.0 at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*. We also have made available the technical submission specifications for the LTCH CARE Data Set version 3.00 at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html*.

In fall 2015, prior to the implementation of new quality measures and new items of LTCH CARE Data Set version 3.00, we intend to offer free trainings to LTCH providers and interested stakeholders. This training is part of our ongoing strategy to ensure successful implementation of the LTCH QRP. In addition, we will continue to maintain and provide guidance through the LTCH help desk via *LTCHQualityQuestions@cms.hhs.gov*. We invite LTCHs to submit specific inquires related to LTCH CARE Data Set version 3.00 via email at the address provided.

Comment: Several commenters supported the intent of this measure, but provided recommendations regarding risk adjustment of the pressure ulcer measure. Commenters suggested modifications, including risk adjustment for patients with multiple-organ failure, for patients on dialysis, and for patients with morbid obesity. One commenter recommended ongoing evaluation of the risk adjustment methodology to ensure it is appropriate for standardized cross-setting risk adjustment purposes.

Another commenter was concerned that the measure is limited to only high risk patients or residents, and that the denominator size is decreased by excluding individuals who are low risk. The commenter indicated that that pressure ulcers do develop in low-risk individuals and that this exclusion will impact each PAC setting differently because the prevalence of low risk individuals varies across settings. The commenter suggested that CMS use a logistic regression model for risk adjustment to allow for an increase in the measure sample size by including all admissions, take into consideration low-volume providers, and capture the development of pressure ulcers in low-risk individuals. This commenter expressed concern that the current risk factors for this measure were selected for the SNF setting and are therefore inappropriate for the LTCH setting, and recommended use of an ordinal scale related to an increasing number and severity of risk factors rather than grading risk dichotomously (for example, high risk vs. low risk). The commenter further recommended additional risk stratification and expanding the list of risk factors to better capture variation across different PAC settings. Finally, the commenter noted that the TEP that evaluated this cross-setting pressure ulcer measure recommended that CMS consider modifying the risk adjustment model and either excluding or risk adjusting for Hospice patients and patients receiving end-of-life care.

Response: We thank the commenters for their support of this measure and for their specific recommendations to inform and improve risk adjustment for this measure. Section 1899B(c)(3)(B) of the IMPACT Act states that quality measures shall be risk-adjusted, as determined appropriate by the Secretary.

In regard to the commenter who recommended we risk adjust using a logistic regression model and incorporate low risk patients into the measure, we believe that this commenter may have submitted comments regarding the wrong quality measure. Their comments apply to the quality measure, Percent of High Risk Residents with Pressure Ulcers (Long Stay) (NQF #0679), which is not the measure that we proposed for the LTCH QRP. The proposed measure is Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678). This measure is currently risk-adjusted using a logistic regression model and includes low-risk patients. In the model, patients are categorized as either high or low risk for four risk factors: functional limitation, bowel incontinence, diabetes or peripheral vascular disease (PVD)/peripheral arterial disease (PAD), and low body mass index (BMI). Low-risk patients are included in the measure calculation. An expected score is calculated for each patient or resident using that patient or resident's risk level on the four risk factors described above. The patient/resident-level expected scores are then averaged to calculate the facility-level expected score, which is compared to the facility-level observed score to calculate the adjusted score for each facility. Additional detail regarding risk adjustment for this measure is available in the measure specifications, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Long-Term-Care-Hospital-Quality-Reporting-Program-Specifications-for-the-Quality-Measures-Proposed-through-the-Fiscal-Year-2016-*

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We have determined that the current risk-adjustment methodology is appropriate for this measure and have developed and implemented the risk adjustment model for this measure. To arrive at this determination, we rely on ongoing measure development and measure maintenance activities undertaken by our measure development contractor, RTI International. These activities include a review of the relevant literature, careful analyses to examine the appropriateness of current and additional risk factors using facility-level data submitted by over 400 LTCHs nationwide by means of the LTCH CARE Data Set as part of the LTCH QRP, input from a LTCH-setting-specific TEP, input from a cross-setting TEP, and advisement and clinical guidance of subject matter experts and other stakeholders to examine current risk factors and to identify additional risk factors.

We recognize that it is important to continue to examine additional risk-adjustment factors to ensure valid and reliable quality measures and to consider further improvement of the risk adjustment model for our quality measures for the LTCH QRP. To this end, we will take into consideration the TEP discussion and these commenters' thoughtful feedback to inform our ongoing assessment of risk factors and future risk adjustment and stratification model for the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure, including consideration of the recommendation to exclude or adjust for hospice patients and patients receiving end-of-life care. We remain committed to conducting ongoing testing and measure development activities in an effort to improve the risk adjustment of quality measures implemented through the quality reporting programs. These activities will ensure that this quality measure remains valid and reliable and provides usable information to inform quality improvement activities within the LTCH setting as well as other PAC settings, and to fulfill the public reporting goals of the CMS quality reporting programs, including the LTCH QRP.

Comment: One commenter asked CMS to clarify how discharges paid under the LTCH PPS standard Federal payment rate versus the LTCH PPS site neutral rate will be included in the quality metrics in the future years. This commenter noted that if there is no differentiation in the quality metrics for the two different types of payment methodologies, it is likely that the quality metrics could become skewed. The commenter also asked CMS whether the metrics can be reported separately for discharges that are paid under the LTCH PPS standard Federal payment rate versus the LTCH PPS site neutral rate and further recommended that all LTCH appropriate metrics should be risk-adjusted.

Response: We refer readers to our response to the preceding comment regarding current and future risk adjustment for this measure. At this time, all LTCH patients that meet the sample inclusion criteria for this measure, irrespective of payer source and payment methodology, are included in this measure. We will take commenter's recommendations regarding analysis and separate reporting for discharges that are paid under the LTCH PPS standard Federal payment rate versus the LTCH PPS site neutral rate under advisement to inform future analyses of the data for the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure.

Comment: Several commenters expressed concern regarding the reliability and validity of this measure across the different PAC settings. The commenters were concerned that the reliability and validity testing for this measure were only conducted in the SNF setting. One commenter stated that the populations in which the data collection tools are used and risk factors in LTCH, IRF, and SNF settings are not similar. The commenter highlighted differences in LTCH clinical characteristics and susceptibility to pressure ulcers amongst LTCH patients as compared to IRF and SNF patient/resident populations, stating that these differences make the application of reliability testing results from the SNF resident population to the LTCH and IRF patient populations inaccurate. The commenter encouraged CMS to conduct additional testing on the reliability and validity of this quality measure using data from LTCHs, IRFs, and SNFs to accurately assess the appropriate use of MDS 3.0 items across settings.

Response: We appreciate the commenters' concern that the LTCH, IRF and SNF populations are not identical and that some differences may exist in the reliability and validity of the measure across settings. We are working towards standardizing data across PAC settings as mandated in the IMPACT Act. As such, we continue to conduct measure development and testing to explore the best way to standardize quality measures, while ensuring reliability and validity for the measures to appropriately account for the unique differences in populations across PAC settings.

The application of this quality measure for use in the LTCH QRP and IRF QRP was established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51750) and the IRF PPS FY 2012 (76 FR 47876 through 47878) when this quality measure was finalized for use in the LTCH QRP and IRF QRP, respectively. The NQF endorsement was expanded to the LTCH and IRF settings in 2012. The expanded measure was finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863) and the FY 2014 IRF PPS final rule (78 FR 47911 through 47912) for use in the LTCH and IRF QRP, respectively. As part of NQF endorsement maintenance for this measure, CMS and our measure contractor will continue to perform reliability and validity testing. Findings from early data analyses have shown that the measure continues to be valid and reliable for LTCH and IRF settings in addition to the SNF/NH setting.

Comment: One commenter was concerned that the pressure ulcer measure is not standardized across PAC settings. The commenter stated that although the measure appears meets the goals and the intent of the IMPACT Act, it does not use a single data assessment tool.

The commenter specifically mentioned the frequency of assessments, highlighting the fact that the LTCH and IRF versions of the measure are calculated using data from assessments conducted at two points in time (admission and discharge), while the SNF version uses assessments at more than two points in time. The commenter expressed concern that the higher frequency of assessments for the MDS could potentially result in higher rates of pressure ulcer counts for SNFs. Another commenter voiced particular concerns regarding differences in the look back periods, for the items used on the IRF, SNF and LTCH assessments (MDS = 7-day assessment period; IRF = 3-day assessment period; LTCH = 3-day assessment period) and suggested that this would result in different rates of detection of new or worsened ulcers. Commenters encouraged CMS to address all of these discrepancies, and suggested that CMS should switch to using only an admission and discharge assessment in the SNF version of the measure.

Response: We appreciate the commenters' review of the measure specifications across the post-acute care settings. We wish to clarify that while

the IMPACT Act requires the modification of PAC assessment instruments to revise or replace certain existing patient assessment data with standardized patient assessment data as soon as practicable, it does not require a single data collection tool. We intend to modify the existing PAC assessment instruments as soon as practicable to ensure the collection of standardized data. While we agree that it is possible that within the PAC assessment instruments certain sections could incorporate a standardized assessment data collection tool, for example, the Brief Interview for Mental Status (BIMS), we have not yet concluded whether this kind of modification of the PAC assessment instruments is necessary.

As to the concern that the pressure ulcer measure calculation is based on more frequent assessments in the SNF setting than in the LTCH and IRF settings, we wish to clarify that result of the measure calculation for all three PAC providers is the same. For all three PAC providers, the measure calculation ultimately shows the difference between the number of pressure ulcers present on admission and the number of new or worsened pressure ulcers present on discharge. While SNF measure calculation arrives at that number differently than does the measure calculation in the IRF and LTCH settings, ultimately all three settings report the same result—as noted, the difference between the number of pressure ulcers present on admission and the new or worsened pressure ulcers at discharge. To explain, in IRFs and LTCHs, pressure ulcer assessment data is obtained only at two points in time—on admission and on discharge. Therefore, the calculation of the measure includes all new or worsened pressure ulcers since admission. In contrast, in SNFs, pressure ulcer assessment data is obtained on admission, at intervals during the stay (referred to as ''interim assessments''), and at discharge. Each interim assessment and the discharge assessment only look back to whether there were new or worsened pressure ulcers since the last interim assessment. The sum of number of new or worsened pressure ulcers identified at each interim assessment and at the time of discharge yields the total number of new or worsened pressure ulcers that occurred during the stay and that were present on discharge. In other words, the collection of pressure ulcer data in LTCHs and IRFs is cumulative, whereas in SNFs, data collection is sequential. In both cases the calculation reaches the same result—the total number of new or worsened pressured ulcers between admission and discharge. Thus, this is the same result of the measure calculation for SNFs as is obtained for IRFs and LTCHs.

We interpret the commenter's concern related to a higher frequency of assessments for the MDS potentially resulting in higher rates of pressure ulcer counts pertains to the potential inclusion of wounds that are new or worsened and are identified on such interim assessments but actually heal by the time of discharge. We wish to clarify that, as with the LTCH and IRF measure calculation that does not include pressure ulcers that heal, we will calculate the quality measure such that any new or worsened pressure ulcer wounds found on interim assessments but have healed will not be included.

In regard to the commenter's concern about different look-back periods, we acknowledge that although the LTCH CARE Data Set and IRF–PAI allow up to the third day starting on the day of admission as the assessment period and the MDS allows for an assessment period of admission up to day 7, we note that the training manuals for SNFs, LTCHs and IRFs provide specific and equivalent-coding instructions related to the items used to calculate this measure (found in Section M—skin conditions for all three assessments). These instructions ensure that the assessment of skin integrity occurs at the initiation of patients' or residents' PAC stays regardless of setting. All three manuals direct providers to complete the skin assessment for pressure ulcers present on admission as close to admission as possible, ensuring a harmonized approach to the timing of the initial skin assessment. Regardless of differences in the allowed assessment periods, providers across PAC settings should adhere to best clinical practices, established standards of care, and the instructions in their respective training manuals, to ensure that skin integrity information is collected as close to admission as possible. Although the manual instructions are harmonized to ensure assessment at the beginning of the stay, based on the commenter's feedback, we will take into consideration the incorporation of uniform assessment periods for this section of the assessments.

Comment: One commenter expressed concern that this measure is NQF-endorsed for the SNF setting and suggested that CMS delay implementing the cross-setting measure until it is NQF-endorsed across all PAC settings. The commenter urged CMS to request formal NQF review, using the Consensus Development Process rather than ''time-limited review'' of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure for the LTCH setting before adopting the measure for the LTCH QRP. The commenter also encouraged CMS to convene a TEP that includes representatives from the LTCH setting to review the applicability of this measure to the LTCH setting, and noted that the NQF MAP only conditionally supported this quality measure for the LTCH QRP. In addition, the commenter expressed concern that the specifications available on the NQF Web site are dated October 2013.

Response: Although the proposed pressure ulcer measure was originally developed for the SNF/nursing home populations, it has been respecified for the LTCH and IRF settings, underwent review for expansion to the LTCH and IRF settings by the NQF Consensus Standards Approval Committee (CSAC) on July 11, 2012 [315] and was subsequently ratified by the NQF Board of Directors for expansion to the LTCH and IRF settings on August 1, 2012.[316] As reflected on the NQF Web site, the endorsed settings for this measure include Post-Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post-Acute/Long Term Care Facility: Long Term Acute Care Hospital, Post-Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility.[317] NQF endorsement of this measure for the LTCH setting indicates that NQF supports the use of this measure in the LTCH and IRF settings, as well as in the SNF setting. This measure was fully supported by the MAP for cross-setting use at its meeting of February 9, 2015. With regard to the comment regarding the measure specifications posted on the NQF Web site, we note that the most up-to-date version of the measure specifications were posted for stakeholder review at the time of the proposed rule on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Long-Term-Care-Hospital-Quality-Reporting-Program-Specifications-for-the-Quality-Measures-Proposed-through-the-Fiscal-Year-2016-*

[315] Nation Quality Forum, Consensus Standardbreds Approval Committee. Meeting Minutes, July 11, 2012. 479–489.

[316] National Quality Forum, Consensus Standards Approval Committee. Meeting Minutes, July 11, 2012. 479–489.

[317] National Quality Forum. Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay). Available: *http://www.qualityforum.org/QPS/0678*.

Notice-of-Proposed-Rule-Making-report.pdf. The specifications posted on the NQF Web site for the quality measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) during the comment period are computationally equivalent and have the same measure components as those posted on the CMS Web site at the time of the proposed rule. However, we provided more detail in the specifications posted with the proposed rule, in an effort to more clearly explain aspects of the measure that were not as clear in the NQF specifications. In addition, we clarified language to make phrasing more parallel across settings, and updated item numbers and labels to match the 2016 data sets (MDS 3.0, LTCH CARE Data Set, and IRF–PAI). We are working closely with NQF to make updates and ensure that the most current language and clearest version of the specifications are available on the NQF Web site.

In addition to NQF review, this measure has been reviewed by several TEPs, which included representatives from the LTCH setting. In June and November 2013, our measure development contractor convened a cross-setting pressure ulcer TEP, which included representatives from the LTCH setting and provided detailed input regarding the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).[318] An additional cross-setting TEP, which also included representatives from the LTCH setting, was convened in February 2015 and provided input on the technical specifications of this quality measure, as well as the applicability of this measure as a cross-setting measure applied across PAC settings, including the LTCH setting, to meet the requirements of the IMPACT Act.[319] Finally, an LTCH-specific TEP provided recommendations regarding this measure in January [320] and September 2011.[321]

As noted, this measure was fully supported by the MAP at their meeting on February 9, 2015 for use in the LTCH QRP as a cross-setting quality measure.[322] The MAP noted that this measure is NQF-endorsed for, and already implemented in, the LTCH QRP. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750) for details on our efforts to solicit and engage technical experts from the LTCH setting as part of our adoption of this measure for the LTCH QRP. We also refer readers to our earlier response on our measure developer's ongoing efforts to further develop this measure and note that we remain committed to soliciting ongoing input and working closely with LTCH, IRF, SNF/nursing home and cross-setting stakeholders and clinical experts as part of our ongoing measure development and maintenance efforts.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure for the FY 2018 payment determination and subsequent years to fulfill the requirements of the IMPACT Act.

c. Finalized Measure To Address the IMPACT Act: Quality Measure Addressing the Domain of Incidence of Major Falls: Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674)

Section 1899B of the Act directs the Secretary to specify quality measures on which PAC providers are required under the applicable reporting provisions to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is the incidence of major falls. The specified application date by which the Secretary must specify quality measures to address this domain for IRFs, SNFs, and LTCHs is October 1, 2016, and for HHAs is January 1, 2019. To satisfy these requirements, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24601 through 24602), we proposed to adopt an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure in the LTCH QRP as a cross-setting quality measure that addresses the domain of incidence of major falls. The purpose of our proposal was to establish this measure's use as a cross-setting measure that satisfies the required adoption of such a measure under the domain of falls with major injury. There is no difference between this measure and the measure we previously adopted, beyond the proposed intent to use the measure to satisfy the requirements of the IMPACT Act. Data collection would start on April 1, 2016. The reporting of data for this measure would affect the payment determination for FY 2018 and subsequent years.

For the LTCH setting, this measure would report the percentage of patients who experienced one or more falls with major injury during the LTCH stay. This measure was developed by CMS and is NQF-endorsed, currently for long-stay residents of nursing facilities. It was adopted for the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877). In the FY 2015 IPPS/LTCH PPS final rule, we adopted a revised start for data collection of April 1, 2016 and affecting FY 2018 payment determination, and we adopted data collection and submission timelines for the FY 2018 payment determination and subsequent years. For information on the detailed rationale for relevance, evidence, appropriateness, importance, and applicability of this quality measure in the LTCH QRP, we refer readers to these final rules.

Measure specifications are available on the NQF Web site at: *http://www.qualityforum/QPS/0674*.

The IMPACT Act requires the implementation of quality measures and resource use and other measures that are standardized and interoperable across PAC settings as well as the reporting of standardized patient assessment data and other necessary data specified by the Secretary. The Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure is NQF-endorsed for long-stay residents of nursing facilities and has been successfully implemented in such settings. The NQF-endorsed measure has been in use as part of the CMS Nursing Home Quality Initiative since

[318] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013 (Chapter 5). Available: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf*

[319] RTI International. Summary of Feedback from the Technical Expert Panel (TEP) Regarding Cross-Setting Measures Aligned with the IMPACT Act. Centers for Medicare & Medicaid Services, April 2015. Available: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/SUMMARY-OF-FEEDBACK-FROM-THE-TECHNICAL-EXPERT-PANEL-TEP-REGARDING-CROSS-SETTING-MEASURES-ALIGNED-WITH-THE-IMPACT-ACT-OF-2014-Report.pdf*.

[320] Thaker, S., Gage, B., Bernard, S., and Nguyen, K. Technical Expert Panel Report: Quality Measures for Long-Term Care Hospitals. Centers for Medicare & Medicaid Services, January 2011.

[321] Thaker, S., Nguyen, K., Berzin, O., Shadle, J., and Bernard, S. Technical Expert Report: Summary of Long-Term Care Hospital Technical Expert Panel Meeting. Centers for Medicare & Medicaid Services, September 2011.

[322] National Quality Forum; Measure Application Partnership (MAP). February 2015. MAP PAC–LTC Programmatic Deliverable—Final. Available: *https://www.qualityforum.org/Publications/2015/02/MAP_PAC-LTC_Programmatic_Deliverable_-_Final_Report.aspx*.

2011. In addition, the measure is currently reported on the CMS *Nursing Home Compare* Web site at: *http://www.medicare.gov/nursinghomecompare/search.html*. As noted previously, this measure was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291), we revised the data collection start date for this measure with data collection to begin starting April 1, 2016, and we adopted data collection and submission timelines for the FY 2018 payment determination and subsequent years.

We reviewed the NQF's consensus endorsed measures and did not identify any NQF-endorsed cross-setting quality measures focused on falls with major injury applicable to multiple PAC settings. We are unaware of any other cross-setting quality measures for falls with major injury that have been endorsed or adopted by another consensus organization. Therefore, we proposed an application of the measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure under the Secretary's authority to select non-NQF-endorsed measure.

A TEP convened by our measure development contractor provided input on the measure specifications, as well as the feasibility and clinical appropriateness of implementing the measure across PAC settings, including the LTCH setting. The TEP supported the implementation of this measure across PAC settings and also supported CMS' efforts to standardize this measure for cross-setting development. In addition, the MAP met on February 9, 2015, and provided input to CMS on the measure. The MAP conditionally supported the use of an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure in the LTCH QRP as a cross-setting quality measure. More information about the MAP's recommendations for this measure is included in The MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act: Final Report which is available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

More information on the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure can be found on the NQF Web site at: *http://www.qualityforum.org/QPS/0674*. Updated specifications and details regarding the changes made to further harmonize this measure across PAC settings are located at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

We proposed that data for this proposed quality measure be collected using the LTCH CARE Data Set, with submission through the QIES ASAP system. For more information on LTCH QRP reporting through the QIES ASAP system, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*. Data collected through a revised LTCH CARE Data Set would be used to calculate this quality measure. Consistent with the LTCH CARE Data Set reporting requirements, the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure would apply to all patients discharged from LTCHs. Data items in the revised LTCH CARE Data Set version 3.00 would include: J1800, Any Falls Since Admission; and J1900, *Number of Falls Since Admission*.

The calculation of the proposed application of the measure would be based on item J1900C, *Number of Falls with Major Injury Since Admission*. The measure specifications for the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*. We refer readers to section VIII.C.9.b. of the preamble of this final rule for more information on the data collection and submission timeline for this proposed quality measure.

We invited public comment on our proposal to adopt an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure, with data collection beginning on April 1, 2016 for the FY 2018 payment determination and subsequent years to fulfill the requirements in the IMPACT Act.

Comment: One commenter supported the proposal to implement an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure to fulfill the requirements of the IMPACT Act.

Response: We thank the commenter for their support of our proposal.

Comment: Several commenters supported the Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure in concept, but suggested that risk adjustment is necessary to ensure reliable and valid comparisons across settings and to account for factors outside of the control of providers for public reporting purposes. One commenter stated that risk adjustment is important when discussing and analyzing falls risk factors in other PAC settings. The commenters also noted that the NQF MAP conditionally supported the falls measure if risk-adjustment were performed.

Response: We appreciate the commenters' concerns that the proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) should be risk-adjusted. The application of risk adjustment, as stated by the IMPACT Act, is ''as determined appropriate by the Secretary'' under section 1899B(c)(3)(B) of the Act.

While we acknowledge that patient characteristics that elevate the risk for falls with major injury vary across the LTCH population, a TEP convened in 2009 by the measurement development contractor asserted that risk adjustment of this quality measure concept was inappropriate because it is each facility's responsibility to take steps to reduce the rate of injurious falls, especially since such events are considered to be ''never events.'' We note that the PAC PRD did not analyze falls with major injury, as falls with major injury was not an assessment item that was tested. However, as the commenter pointed out, the prevalence of a history of falls prior to the PAC admission did vary across post-acute settings (as assessed by Item B7 from the CARE tool: ''History of Falls. Has the patient had two or more falls in the past year or any fall with injury in the past year?''). Nonetheless, we believe that as part of best clinical practice, LTCHs should assess residents for falls risk and take steps to prevent future falls with major injury.

A TEP of LTCH experts convened in 2011 agreed that falls with major injury are very important to track in LTCHs and did not recommend risk adjustment for this measure. The numerator, denominator, and exclusions definitions provided to the TEP in 2015 are virtually identical to the specifications we proposed to adopt for this measure, and did not include risk adjustment. Two out of 11 members of the 2015 TEP supported risk adjustment of the falls measure. For more information on the 2015 TEP, please visit *http://*

www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/SUMMARY-OF-FEEDBACK-FROM-THE-TECHNICAL-EXPERT-PANEL-TEP-REGARDING-CROSS-SETTING-MEASURES-ALIGNED-WITH-THE-IMPACT-ACT-OF-2014-Report.pdf.

We believe factors that increase the risk of falling, such as cognitive impairment, should be included by facilities in their risk assessment to support proper care planning. As cited in the proposed rule, research suggests that 78 percent of falls are anticipated falls, occurring in individuals who could have been identified as at-risk for a fall using a risk-assessment scale. Risk adjusting for falls with major injury could unintentionally lead to insufficient risk prevention by the provider. As required by the DRA, the Hospital Acquired Conditions-Present On Admission (HAC–POA) Indicator Reporting provision requires a quality adjustment in the Medicare Severity-Diagnosis Related Groups (MS–DRG) payments for certain Hospital Acquired Conditions (HACs), which include falls and trauma, and these payment reductions are not risk adjusted. The need for risk assessment, based on varying risk factors among patients, does not remove the obligation of providers to minimize that risk.

With regard to the MAP recommendation to risk adjust this measure cited by the commenter, the MAP feedback regarding risk adjustment for this quality measure applied to the home health setting, not to the SNF setting. We also refer readers to a more recent Cochrane review of 60 randomized controlled trials, which found that within care facilities, multifactorial interventions have the potential to reduce rates of falls and risk of falls.[323]

Comment: One commenter stated that data collection and abstraction from the medical record for this measure would pose a burden on LTCHs because of separate systems for gathering data for such events.

Response: We appreciate the concerns related to any undue burden, including data collection, documentation, and reporting and we take such concerns under consideration when selecting measures for the LTCH QRP. The Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure includes the following two data elements in the LTCH CARE Data Set version 3.00: J1800, *Any Falls Since Admission,* and J1900, *Number of Falls Since Admission.* If the provider answers ''No'' to J1800, *Any Falls Since Admission,* then J1900, *Number of Falls Since Admission,* may be skipped. Based on evidence and rationale we presented in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877) to support our selection and finalization of our proposal to adopt this measure for the LTCH QRP, we believe the impact this measure could have on quality of care and patient outcomes in the LTCH setting justifies additional resources needed for measure data collection and data submission.

In addition, we note that this measure was previously finalized for use in the LTCH QRP through the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877), and our proposal of this previously adopted measure to establish its cross-setting use, in order to address the domain of incidence of major falls to meet the requirements of the IMPACT Act, does not add any additional burden for LTCHs.

Comment: Several commenters recommended re-specifying and testing the measure in the LTCH setting and obtaining NQF endorsement specifically for the LTCH setting prior to implementation in the LTCH QRP.

Response: We appreciate the commenters' recommendations regarding NQF endorsement in the LTCH setting and recognize that it is an important step in the measure development process. However, because falls with major injury is an important patient safety concern in LTCHs, and because of the lack of availability of NQF-endorsed measures for the LTCH setting or measures endorsed by any other consensus organizations, we proposed this measure under the exception authority provided in section 1899B(e)(2)(B) of the Act, which allows us to apply a measure to the LTCH setting that is not NQF-endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

There is no difference between this measure and the measure we previously adopted through the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877).

We also are clarifying that while this measure is currently endorsed for the nursing home setting, we believe the data collection items, measure definition, and measure specifications are applicable across multiple PAC settings, including the LTCH setting (78 FR 50876). With regard to the adequacy of the measure's testing, the item-level testing during the development of the MDS 3.0 (data elements in the LTCH CARE Data Set were adapted from MDS 3.0) showed near-perfect inter-rater reliability for the MDS item (J1900C) used to identify falls with major injury. The NQF measure evaluation criteria do not require measure-level reliability if item reliability is high. However, we believe that, given the overlap in the populations and item-level testing results, the application of this measure for LTCH patients will be reliable. In addition, we intend to test the measure for the LTCH setting once data collection begins as part of LTCH QRP and as part of ongoing maintenance of the measure for NQF endorsement.

In addition, our measure development contractor convened a TEP in 2011 that supported the importance of a quality measure to address falls with a major injury in the LTCH setting. This measure on reports falls with major injuries which is an important patient safety concern for LTCH patients. For the reasons listed above, we have concluded that this measure is appropriate for LTCH patients.

Comment: One commenter stated that the falls measure is not fully specified as a cross-setting measure. This commenter suggested that CMS needs to more clearly specify the numerator, denominator and exclusions, including risk adjustment for this quality measure. Therefore, this measure should not be implemented as proposed since the specifications in the proposed rule differ from those in referenced documents, NQF applications for the measures, and the IRF and SNF proposed rules.

Response: This quality measure was proposed and specified as a cross-setting measure for LTCH, IRF, and SNF settings. The Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure is the same measure for each setting. Additional details on the measure specifications for the application of this measure to the LTCH setting in order to harmonize this measure across LTCH, IRF, and SNF settings to meet the IMPACT Act requirements are available for download at: *http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

With regard to the measure specifications posted on the NQF Web site, the most up-to-date version of the measure specifications were posted for stakeholder review at the time of the

[323] Cameron ID, Gillespie LD, Robertson MC, Murray GR, Hill KD, Cumming RG, Kerse N. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database of Systematic Reviews* 2012, Issue 12. Art. No.: CD005465. DOI: 10.1002/14651858.CD005465.pub3.

proposed rule on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Skilled-Nursing-Facility-Quality-Reporting-Program-Quality-Measure-Specifications-for-FY-2016-Notice-of-Proposed-Rule-Making-report.pdf*. The specifications currently posted on the NQF Web site are computationally equivalent and have the same measure components as those posted on the CMS Web site at the time of the proposed rule. However, we provided more detail in the specifications posted with the proposed rule, in an effort to more clearly explain aspects of the measure that were not as clear in the NQF specifications. In addition, we clarified language to make phrasing more parallel across settings, and updated item numbers and labels to match the 2016 data sets (MDS 3.0, LTCH CARE Data Sets, and IRF–PAI). We are working closely with NQF to make updates and ensure that the most current language and clearest version of the specifications are available on the NQF Web site.

After consideration of the public comments we received, we are finalizing our proposal to adopt the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure, with data collection beginning on April 1, 2016, for the FY 2018 payment determination and subsequent years to fulfill the requirements in the IMPACT Act.

d. Finalized Measure To Address the IMPACT Act: Quality Measure Addressing the Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015)

Section 1899B(c)(1) of the Act directs the Secretary to specify quality measures on which PAC providers are required under the applicable reporting provisions to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is functional status, cognitive function, and changes in function and cognitive function. The specified application date by which the Secretary must specify quality measures to address this domain for IRFs and SNFs is October 1, 2016, for LTCHs is October 1, 2018, and for HHAs is January 1, 2019. To satisfy these requirements, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24602 through 24605), we proposed to adopt an application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on 07/23/2015) measure that we have already adopted in the LTCH QRP as a cross-setting quality measure that addresses the domain of functional status, cognitive function, and changes in function and cognitive function. The reporting of data for this measure would affect the payment determination for FY 2018 and subsequent years. This quality measure reports the percent of patients with both an admission and a discharge functional assessment and a goal that addresses function.

The National Committee on Vital and Health Statistics, Subcommittee on Health,[324] noted: ''[i]nformation on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations, in other words, their functional status.'' This statement is supported by research showing that patient functioning is associated with important patient outcomes, such as discharge destination and length of stay in inpatient settings,[325] as well as the risk of nursing home placement and hospitalization of older adults living in the community.[326] Functioning is important to patients and their family members.[327] [328] [329]

The majority of patients who receive PAC services, such as care provided by SNFs, HHAs, IRFs and LTCHs, have functional limitations, and many of these patients are at risk for further decline in function due to limited mobility and ambulation.[330] The patient and resident populations treated by SNFs, HHAs, IRFs and LTCHs vary in terms of their functional abilities at the time of the PAC admission and their goals of care. For IRF patients and many SNF residents, treatment goals may include fostering the patient's ability to manage his or her daily activities so that the patient can complete self-care and/or mobility activities as independently as possible, and, if feasible, return to a safe, active, and productive life in a community-based setting. For HHA patients, achieving independence within the home environment and promoting community mobility may be the goal of care. For other HHA patients, the goal of care may be to slow the rate of functional decline in order to allow the person to remain at home and avoid institutionalization.[331]

Lastly, in addition to having complex medical care needs for an extended period of time, LTCH patients often have limitations in functioning because of the nature of their conditions, as well as deconditioning due to prolonged bed rest and treatment requirements (for example, ventilator use). The clinical practice guideline Assessment of Physical Function [332] recommends that clinicians should document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge and establishing a functional goal for discharge as part of the care plan (that is, treatment plan) is an important aspect of patient care in all of these PAC settings.

Given the variation in patient and resident populations across the PAC settings, the functional activities that are typically assessed by clinicians for each type of PAC provider may vary. For example, the activity of rolling left and right in bed is an example of a functional activity that may be most relevant for low-functioning patients or residents who are chronically critically

[324] Subcommittee on Health National Committee on Vital Statistics, ''Classifying and Reporting Functional Status'' (2001).

[325] Reistetter TA, Graham JE, Granger CV, Deutsch A, Ottenbacher KJ.: Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. *Archives of Physical Medicine and Rehabilitation,* 2010; 91:345–350.

[326] Miller EA, Weissert WG.: Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. Medical Care Research and Review, 57; 3: 259–297.

[327] Kurz, A. E., Saint-Louis, N., Burke, J. P., & Stineman, M. G.: Exploring the personal reality of disability and recovery: a tool for empowering the rehabilitation process. *Qual Health Res, 18*(1), 90–105 (2008).

[328] Kramer, A. M. (1997). Rehabilitation care and outcomes from the patient's perspective. *Med Care, 35*(6 Suppl), JS48–57.

[329] Stineman, M. G., Rist, P. M., Kurichi, J. E., & Maislin, G.: Disability meanings according to patients and clinicians: imagined recovery choice pathways. *Quality of Life Research, 18*(3), 389–398 (2009).

[330] Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ.: Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

[331] Ellenbecker CH, Samia L, Cushman MJ, Alster K: Patient safety and quality in home health care. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Vol 1.

[332] Kresevic DM.: Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103.

ill. Managing a full flight of stairs may be assessed for higher functioning patients or residents. However, certain functional activities, such as eating, oral hygiene, lying to sitting on the side of the bed, toilet transfers, and walking or wheelchair mobility, are important activities for patients in each PAC setting.

Although functional assessment data are currently collected by SNFs, HHAs, IRFs and LTCHs, this data collection has employed different assessment instruments, scales, and item definitions. The data collected cover similar topics, but are not standardized across PAC settings. Further, the different sets of functional assessment items are coupled with different rating scales, making communication about patient functioning challenging when patients transition from one type of setting to another. Collection of standardized functional assessment data across SNFs, HHAs, IRFs and LTCHs, using common data items, would establish a common language for patient functioning, which may facilitate communication and care coordination as patients transition from one type of provider to another. The collection of standardized functional status data may also help improve patient or resident functioning during an episode of care by ensuring that basic daily activities are assessed at the start and end of each episode of care with the aim of determining whether at least one functional goal has been established.

The functional assessment items included in the proposed functional status quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration (PAC PRD) version of the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize the assessment of patients' status across acute care and PAC settings, including SNFs, HHAs, IRFs and LTCHs. The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge in order to determine patients' or residents' needs, evaluate patient progress and prepare patients or residents and families for a transition to home or to another setting.

The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''The Development and Testing of the CARE Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3.'' [333] Reliability and validity testing were conducted as part of CMS' PAC PRD, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the CARE Item Set: Final Report On Reliability Testing: Volume 2 of 3'' [334] and the report entitled ''The Development and Testing of The CARE Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.'' [335] The reports are available on our Post-Acute Care Quality Initiatives Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html*.

The cross-setting function quality measure we proposed to adopt for the FY 2018 payment determination and subsequent years to meet the IMPACT Act requirements is a process measure that is an application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) measure. This quality measure was developed by the CMS. It reports the percent of patients with both an admission and a discharge functional assessment and a treatment goal that addresses function. The treatment goal provides documentation that a care plan with a goal has been established for the patient.

We proposed to use the data that will be collected and submitted using the LTCH CARE Data Set version 3.00 for the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) measure starting April 1, 2016 in order to calculate this cross-setting application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) quality measure. The items in the cross-setting application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) measure are a subset of the items included in the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) measure, which was finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298). Therefore, the adoption of this quality measure to satisfy the requirements of the IMPACT Act would not result in the addition of new items to the LTCH CARE Data Set version 3.00 and, therefore, would not result in additional burden for data collection and data submission to LTCHs.

This process measure requires the collection of functional status admission and discharge assessment data using standardized clinical assessment items, or data elements that assess specific functional activities, that is, self-care, mobility activities. The self-care and mobility function activities on the LTCH CARE Data Set version 3.00 are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. For this quality measure, documentation of a goal for one of the function items reflects that the patient's care plan addresses function. The function goal is recorded at admission for at least one of the standardized self-care or mobility function items using the 6-level rating scale.

To the extent that a patient had an incomplete stay (for example, for the purpose of being admitted to an acute care facility), collection of discharge functional status data might not be feasible. Therefore, for patients with incomplete stays, admission functional status data and at least one treatment goal would be required; however, discharge functional status data would not be required to be reported.

A TEP convened by our measure development contractor provided input on the technical specifications of this quality measure, as well as the feasibility of implementing the measure across PAC settings, including the LTCH setting. The TEP supported the implementation of this measure across PAC settings and also supported our efforts to standardize this measure for cross-setting use.

In addition, the MAP met on February 9, 2015, and provided input to CMS on the measure. The MAP conditionally supported the use of an application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) measure for use in the LTCH QRP as the cross-setting measure. The conditions stated

[333] Barbara Gage et al: ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI, International, 2012).

[334] Ibid.

[335] Ibid.

by the MAP included that the measure should be endorsed by the NQF. Finally, the MAP reiterated its support for adding measures addressing function, noting the group's special interest in this PAC/LTC core concept. More information about the MAP's recommendations for this measure is discussed in The MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act: Final Report which is available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

The measure we proposed is an Application of the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631: endorsed on 07/23/2015). The proposed measure is derived from the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function quality measure. The specifications are available for review at the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures focused on assessment of function for PAC patients. We are also unaware of any other cross-setting quality measures for functional assessment that have been endorsed or adopted by another consensus organization. Therefore, we proposed to adopt this functional assessment measure for use in the LTCH QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority to select non-NQF-endorsed measures.

As discussed previously, we proposed that this cross-setting quality measure use a subset of data collected for Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) using the LTCH CARE Data Set, with submission through the QIES ASAP system. For more information on LTCH QRP reporting through the QIES ASAP system, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

We described the measure calculation algorithm for this measure in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24605).

This measure is calculated at two points in time, at admission and discharge (we refer readers to section VIII.C.9.b. of the preamble of this final rule, Form, Manner and Timing of Quality Data Submission, for more information on the proposed data collection and submission timeline for this proposed quality measure).

The items would assess specific self-care and mobility activities, and would be based on functional items included in the PAC PRD version of the CARE Item Set. The items have been developed and tested for reliability and validity in SNFs, HHAs, IRFs, and LTCHs. More information pertaining to item testing is available on our Post-Acute Care Quality Initiatives Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html*.

We invited public comments on our proposal to adopt the Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) measure that we have already adopted in the LTCH QRP as a cross-setting quality measure that addresses the domain of functional status, cognitive function, and changes in function and cognitive function to satisfy the requirement of the IMPACT Act, with data collection starting on April 1, 2016, for the FY 2018 payment determination and subsequent years. Further, we invited public comments on our proposal to use a subset of data collected for the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) measure to meet the requirements for this cross-setting quality measure that addresses the domain of functional status, cognitive function, and changes in function and cognitive function to satisfy the requirement of the IMPACT Act.

Comment: MedPAC did not support the adoption of the function process measure in the LTCH QRP, NQF #2631; endorsed on 07/23/2015 and urged CMS to adopt outcomes measures focused on changes in patient physical and cognitive functioning while under a provider's care.

Response: We appreciate MedPAC's preference for moving toward the use of functional outcome measures in order to assess the patient's physical and cognitive functioning under a provider's care. We believe that the use of this process measures at this time will give us the data we need to develop a more robust outcome-based quality measure on this topic in the future. The proposed function quality measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), has attributes to enable outcomes-based evaluation by the provider. Such attributes include the assessment of functional status at two points in time, admission and discharge, enabling the provider to identify, in real time, changes, improvement or decline, as well as maintenance. In addition, the proposed quality measure requires that the provider indicate at least one functional goal associated with a functional activity, and the provider can calculate the percent of patients who meet goals. Such real time use enables providers to engage in person-centered goal setting and the ability to use the data for quality improvement efforts.

In addition, we note that for the LTCH QRP, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301), we adopted an outcome measure, Functional Outcome Measure: Change in Mobility Among LTCH Patients Requiring Ventilator Support (NQF #2632; endorsed on 07/23/2015), for implementation starting April 1, 2016.

Comment: One commenter supported inclusion of the quality measure an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015). The commenter noted that this cross-setting measure, which is focused on function, addresses measure shortcomings in the LTCH QRP and other QRPs.

Response: We appreciate the commenter's support of this measure. We agree that patient functioning is an important area of quality in PAC settings, including the LTCH setting.

Comment: Several commenters expressed concern related to undue burden associated with data documentation for the functional status quality measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015).

Response: We appreciate the concerns related to any undue burden, including documentation, and take such concerns under consideration when selecting measures for the LTCH QRP. We aim to adopt quality measures that rely on data

that is already collected in clinical practice.

To reduce potential burden associated with collecting additional items, we have included several mechanisms in Section GG of the LTCH CARE Data Set that allow the clinician to skip questions in the data set that are not appropriate for an individual patient in order to reduce burden. We have instituted skip options so that the final number of items assessed per patient is limited depending on their complexity and capabilities. Therefore, although all of the items are available for assessment, we have built in mechanism that enables the assessor to include assessment information as, and when, appropriate.

We further note that there is no new burden associated with this process measure since it will utilize data elements in the LTCH CARE Data Set that are already collected for the previously adopted measure, Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015).

Comment: Several commenters noted that the measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), does not capture functional outcomes. One commenter encouraged CMS to propose functional outcome measures for LTCHs, SNFs and HHAs in future rulemaking for quality of care and payment.

Response: We recognize stakeholder concerns for the development of outcome-based quality measures. We point out that we previously adopted the functional outcome measure Functional Status Outcome Measure: Change in Mobility Among LTCH Patients Requiring Ventilator Support (NQF #2632; endorsed on 07/23/2015) in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301), and data collection for this outcome measure begins on April 1, 2016.

Further, as discussed above, the measure has attributes within the assessment and data collection that enables outcomes-based evaluation by the provider.

As discussed above, this function quality measure, NQF #2631; endorsed on 07/23/2015, has attributes within the assessment and data collection that enables outcomes-based evaluation by the provider.

The IMPACT Act specifically mentions goals of care as an important aspect of the use of standardized assessment data, quality measures, and resource use to inform discharge planning and incorporate patient preference. We are currently developing functional outcome measures, specifically self-care and mobility quality measures, which may be considered in the future for use in the LTCH setting as part of the LTCH QRP. These outcome function quality measures are being designed to use the same standardized functional assessment items that are included in the cross-setting person and family-centered function process measure in order to capitalize on the data collected for this process measure (that is, an Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015)), which will inform further development, while allowing for the consideration of limited additional burden.

Comment: One commenter noted that the measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), includes reporting of only one goal, even though patients often have multiple functional goals. The commenter indicated that goals may be to improve function or to maintain function.

Response: The quality measure requires a minimum of one goal per patient stay; however, clinicians can report goals for each self-care and mobility item included in Section GG of the LTCH CARE Data Set version 3.00.

We believe that assessing patient function goals should be part of clinical care and builds upon the conditions of participation (CoPs) for LTCH providers. The IMPACT Act also specifically mentions goals of care as an important aspect of the use of standardized assessment data, quality measures, and resource use to inform discharge planning and incorporate resident preference. We agree that, for many PAC patients, the goal of therapy is to improve function, and we also recognize that, for some patients, delaying decline may be the goal. We believe that individual, person-centered goals exist in relation to individual preferences and needs. We will provide instructions about reporting of goals in a training manual and in training sessions to better clarify that goals set at admission may be focused on improvement of function or maintenance of function.

Comment: One commenter noted that goal data was not included in the PAC PRD and expressed concerns about reliability and validity of these items. The commenter requested clarification on how CMS plans to use goal data.

Response: The function measure calls for documentation of a goal as evidence that there is a care plan with a goal in place for each patient. CMS will use the variable of patient goals for data collection and monitoring. By using the data collected in this quality measure, LTCHs can internally monitor functional outcomes, specifically the percent of patients who meet or exceed their discharge functional status goals, as established at admission in conjunction with the patient and family.

Comment: Several commenters expressed concern regarding the use of the CARE Tool (Item Set) as the data source for the functional status quality measures due to limited testing in LTCHs and reliability testing results. The commenters noted that several self-care and mobility items have Kappa statistics categorizing inter-rater reliability as ''fair'' or ''moderate,'' and were based on a small sample of 46 LTCH patients. The commenters stated that ''fair'' or ''moderate'' reliability, while acceptable for exploratory studies or internal quality improvement efforts, is insufficient for national use in the LTCH QRP. Commenters recommended that CMS explain the low Kappa statistics and/or re-test these items in significantly more LTCHs to address reliability issues. The commenters noted that measure testing should be oriented towards the intended setting of use of the measure and suggested additional testing in the LTCH setting be conducted.

Response: The reliability study results mentioned by these commenters were only one of several reliability analyses conducted as part of the PAC PRD. The referenced result was a reflection of the small sample size available for analysis. In addition to the inter-rater reliability study mentioned by these commenters, we also examined: (1) Inter-rater reliability of the CARE items using videotaped case studies, which included 114 LTCH assessments from three LTCHs; and (2) internal consistency of the function data, which included more than 7,700 assessments from 28 LTCHs. The results of these analyses indicate moderate to substantial agreement on the CARE Tool (Item Set) items. The report describing these additional analyses and an interpretation of the Kappa statistics results is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-*

Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-Reliability-Testing-Volume-2-of-3.pdf.

In addition to the PAC PRD analyses, as part of the NQF application process, we conducted additional analyses focused on the six submitted IRF and LTCH function quality measures, including item-level, scale-level and facility-level analyses testing the reliability and validity of the CARE function data. The members of this panel reviewed this measure and concluded that the measure does meet the scientific acceptability requirements at a moderate level. A description of the analyses and the results are available on the NQF Web site's Person- and Family-Centered Care project at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867*. Therefore, given the overall findings of the reliability and validity analysis, we believe these CARE items provide a scientifically sound set to measure quality for the LTCH QRP.

We understand the importance of education in assisting providers to collect accurate data, and we have worked in the past with public outreach including training sessions, training manuals, Webinars, open door forums and help desk support. Further, we note that, as part of the LTCH QRP, we intend to evaluate the national-level data for this quality measure submitted by LTCHs to CMS. These data will inform ongoing measure development and maintenance efforts, including further analysis of reliability and validity of the data elements and the quality measure. Finally, we agree that ongoing reliability and validity testing is critical for all items used to calculate quality measures.

Comment: One commenter suggested that several of the functional status assessment items had low or nonresponse rates and missing data when used as part of PAC PRD. The commenter requested that CMS provide additional information on how the measure has been updated to address these low response rates.

Response: With respect to the comments that some items had low response rates (defined as the utilization of coding responses for when a patient does not or cannot attempt a daily activity, the activity did not occur), the assessor appropriately reported a code indicating the reason that the activity was not attempted (for example, due to a medical condition or due to patient refusal). This is a good practice to ensure that bias is not introduced through missing data not otherwise specified. With some populations, there was a high use of the letter codes indicating that the activity was not able to be coded or collected at the time of the assessment due to patient condition, but there was a very low percentage of missing data.

While activities such as ''toileting hygiene'' and ''walking'' may have high rates of ''activity not attempted'' codes at the time of admission for LTCH patients, these activities are completed more often at discharge. Assessment of these activities is particularly important to assess for LTCH patients returning to their home. Using national Medicare FFS claims data from 2010 through 2013, we examined the percentage of LTCH patients who were admitted from an acute hospital and discharged home. The national percentage of LTCH patients discharged home was 40.1 percent in 2010, 39.5 percent in 2011, 38.4 percent in 2012, and 37.5 percent in 2013. These findings demonstrate that a large proportion of LTCH patients are discharged home directly from the LTCH setting. These data strongly support the importance of functional assessment in the LTCH setting, and ensuring patient safety from a functional perspective prior to discharge. Assessment of a patient's level of independence and safety in performing functional activities such as walking is critical for a safe patient transition from the LTCH to the home setting.

Public input and a TEP in 2013 provided feedback to CMS pertaining to the pattern of scores including that of letter codes. TEP members included experts from LTCHs, as well as IRFs and SNFs. A report summarizing recent TEP meetings focused on functional status quality measures titled ''Summary of Feedback from TEP on the Development of Cross-Setting Functional Status Quality Measures'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*. The functional status quality measure development built on work conducted as part of a project funded by ASPE, and that project also included a cross-setting function quality measure TEP, which was held on August 15, 2012. A report summarizing that meeting is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/ASPE-Report-Analysis-of-Crosscutting-Medicare-Functional-Status-Quality-Metrics-Using-the-Continuity-and-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report.pdf*.

Comment: A few commenters noted that the proposed quality measure is an application of the LTCH measure under review at NQF, and that fewer functional assessment items are in the proposed measure when compared to the LTCH process measure. Therefore, the commenters believe the items in the LTCH CARE Data Set are limited, and functional issues addressed by clinicians may not be represented in this data set.

Response: The quality measure under NQF review, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), was adopted for FY 2018 payment determination and subsequent years as part of the LTCH QRP in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298). In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24602 through 24605), we proposed *an application* of this previously adopted quality measure. That is, the quality measure, *an Application* of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), is a cross-setting measure that is standardized across multiple settings (LTCHs, IRFs, SNFs). This quality measure includes only selected function items from the previously adopted quality measure.

We believe that standardization of assessment items across the spectrum of PAC settings is an important goal. In the cross-setting process measure, there is a common core subset of function items that will allow tracking of patients' functional status across settings. We recognize that there are some differences in patients' clinical characteristics, including medical acuity, across the LTCH, SNF and IRF settings, and that certain functional items may be more relevant for certain patients. Decisions regarding item selection for each quality measure were based on our review of the literature, input from a TEP convened by our measure contractor, our experiences and review of data in each setting from the PAC PRD, and public comments.

To clarify which specific items are included in each function measure for each QRP, we added a table to the document entitled, LTCH QRP: Specifications of Quality Measures Adopted in the FY 2016 Final Rule, which identifies which functional assessment items are used in the cross-setting process measure, as well as the setting-specific IRF and LTCH outcome quality measures. The document is available for download at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-*

Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.

Comment: Several commenters noted that only a few standardized assessment items were proposed by CMS in Section GG of the LTCH CARE Data Set version 3.00 and that the items proposed deviated from the original set of CARE items tested in the PAC PRD. One of these commenters noted the importance of consistent items and assessment instructions across the settings. The commenters also were concerned that the items proposed for IRFs, SNFs and LTCHs were not the same set of items. Some of the commenters questioned the validity of including only a subset of items from the CARE Tool (Item Set) tested in the PAC PRD, diminishing the comparability of the data.

Response: For this quality measure, a core set of function items are included in Section GG of the LTCH CARE Data Set version 3.00 for LTCHs. This core set of function items are also included in Section GG of the IRF–PAI for IRFs and Section GG of the MDS 3.0 for SNFs, respectively. This core set of items selected for cross-setting use were chosen for their applicability across all PAC settings, guided by the TEP convened by our measure development contractor. The core set of items nested in the Section GG were chosen from the set of function-related items tested in the PAC PRD.

The PAC PRD tested a range of items, some of which were duplicative, to identify the best performing items in each domain. Select items were removed from the item set where testing results and clinician feedback suggested the need for fewer items to be included in a particular measure or scale. We also received feedback on the items from a cross-setting TEP convened by our measure development contractor, RTI International. The measure is based on analyses which are available on our Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html*.

We chose from this subset of data items to develop the function-based CARE measures, such as the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) measure. Additional function items are included on the LTCH CARE Data Set due to the adoption of additional outcome-based quality measure (Functional Status Outcome Measure: Change in Mobility Among LTCH Patients Requiring Ventilator Support, NQF #2632; endorsed on 07/23/2015) in the LTCH setting. Therefore, we believe that the core set of items in Section GG are standardized to one another by item and through the use of the standardized 6-level rating scale. Further, we will continue to work to harmonize the assessment instructions to better guide the coding of the assessment, as we believe that this will lead to accurate and reliable data, allowing us to compare the data within each setting. We also believe that the assessment of these activities is part of routine clinical care at a minimum at the start of care and at the end of care.

We recognize that there are some differences in patients' clinical characteristics, including medical acuity across the SNF, LTCH and IRF settings, and that certain functional items may be more relevant for certain patients. For example, one item, ''Wash Upper Body'' is included in the LTCH quality measure, Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), but is not included in the IRF outcome measures or the cross-setting measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), because this item overlaps with the item ''Bathe/Shower Self,'' which focused on washing the entire body. For the LTCH setting, where patients are chronically critically ill, bathing the upper body is more likely to occur than washing the entire body. In IRFs and SNFs, clinicians typically assess showering or bathing of the entire body.

To clarify which function items are included in each function measure for each QRP, we added a table to the document entitled, LTCH QRP: Specifications of Quality Measures Adopted in the FY 2016 Final Rule, which identifies which functional assessment items are used in the cross-setting process measure, as well as the setting-specific IRF and LTCH outcome quality measures. The document is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

Comment: One commenter noted there may be a challenge in determining the baseline cognitive function of LTCH patients, which is one of the items needed for the quality measure, Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015).

Response: We appreciate the commenter's feedback pertaining to the quality measure, an Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015). We are clarifying that the Confusion Assessment Method (CAM©), which includes the item focused on baseline cognitive function, is not required as part of this cross-setting measure. It is required as part of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), which was adopted into the LTCH QRP in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298). We have added a table entitled ''Long-Term Care Hospital Quality Reporting Program—Specifications for the Quality Measures Adopted through the FY 2016 IPPS/LTCH PPS final rule'' to the CMS Web site to clarify which items are required for each functional quality measure, which is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We have addressed similar concerns with training in the past with public outreach including training sessions, training manuals, Webinars, open door forums, help desk support, and a Web site that hosts training information (*http://www.youtube.com/user/CMSHHSgov*). We plan to conduct such activities to support the April 1, 2016 implementation for the new items included in the LTCH CARE Data Set version 3.00.

Comment: Several commenters expressed concern about the lack of risk-adjustment of this measure.

Response: The function quality measure, an Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), is a process measure that focuses on the clinical process of completion of functional assessments and a care plan addressing function. Although the IMPACT Act requires that the cross-setting quality measures be risk-adjusted as determined appropriate by the Secretary, it does not limit the Secretary to adopting outcome measures. Some process measures are

risk adjusted.[336] In the development of an application of the measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; awaiting NQF endorsement), the TEP considered, but did not recommend, the application of a risk adjustment model. We agree with that conclusion because the completion of a functional assessment, which includes the use of ''activity not attempted'' codes, is not affected by the medical and functional complexity of the resident. Therefore, we believe that risk adjustment of this quality measure is not warranted.

Comment: One commenter was concerned that the measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) was not NQF-endorsed.

Response: We agree that the NQF endorsement is an important part of measure development process. We have proposed an application of the quality measure, the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. This quality measure has been has been endorsed by NQF on July 23, 2015. We have a rigorous process of construct testing and measure selection, guided by the TEPs, public comments from stakeholders, and recommendations by the PAC/LTC MAPs.

Comment: Several commenters expressed concern that the proposed function process measure, an Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), does not meet the requirements of the IMPACT Act, because measures must be outcome-based. One commenter asserted that the proposed measure did not satisfy the specified IMPACT Act domain, as the measure is not able to report on changes in function, and one other commenter claimed that the measure does not satisfy the reporting of data on functional status. One commenter suggested that the measure does not meet the mandate, as the measure does not have appropriate numerator, denominator, and exclusions specifications, it lacks NQF endorsement, the proposed quality measure fails to be based on a common standardized assessment tool, and the proposed quality measure lacks evidence that associates the measure with improved outcomes. One commenter claimed that because the specifications for the proposed measure are inconsistent with the measure specifications posted by the NQF for the measure that is under endorsement review, CMS failed to meet the requirements under the IMPACT Act to provide measure specifications to the public, further asserting that one cannot determine the specifications that are associated with the proposed measure, which is an application of the NQF version of the measure. Response: We agree that the use of outcome measures is important. We believe that the proposed function measure meets the requirements of the IMPACT Act. The statute requires, among other things, the submission of data on the quality measures specified in at least the domains identified in the Act, but does not require a particular type of measure (for example, outcome or process) for each measure domain. Further, as discussed above, the measure has attributes within the assessment and data collection that enables outcomes-based evaluation by the provider.

We also disagree with the comment that we failed to provide the specifications to the proposed measure. The proposed function process quality measure is an application of the measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on 7/23/2015). The quality measure was endorsed by NQF on July 23, 2015 and was proposed and finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298) for adoption in the LTCH QRP. An application of this measure was proposed in the FY 2016 SNF QRP proposed rule, and similarly it was proposed in the FY 2016 IPPS/LTCH PPS proposed rule and the FY 2016 IRF PPS proposed rule. We proposed the cross-setting version, an application of the LTCH QRP quality measure, based on guidance from multiple TEPs convened by our measure contractor, RTI International. The specifications for this measure are located on the LTCH Quality Reporting Program Measures Information Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*. These specifications were posted at the time we issued the proposed rule.

As discussed in section VIII.C.6.c. of the preamble of this rule, prior to our consideration to propose this measure's use in the LTCH QRP, we reviewed the NQF's endorsed measures and were unable to identify any NQF-endorsed, cross-setting or standardized quality measures focused on assessment of function for PAC patients/residents. We were also unaware of any other cross setting quality measures for functional assessment that have been endorsed or adopted by another consensus organization. Therefore, we proposed a modified version of the quality measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on 7/23/2015), with such modifications to allow for its cross-setting application in the LTCH QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority to select a non-NQF-endorsed measure. Since the cross-setting measure is not identical to the measure recommended for NQF-endorsement, it is considered an application of the measure.

Comment: One commenter was concerned that the measure specifications posted with the FY 2016 IPPS/LTCH PPS proposed rule differ from those posted with the IRF and SNF proposed rules and that the public would be unable to determine which specifications CMS intends to use. The commenter also was concerned that these differences in specifications, including differences in the measure denominator would impede interoperability across settings. This commenter suggested measures include all patients across all settings, regardless of payer.

Response: As mentioned previously, the quality measure being proposed as a cross-setting measure for LTCH, IRF, and SNF settings, an Application of the Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), is the same measure for each setting. Additional function items are included on the IRF–PAI and LTCH CARE Data Set due to the proposal or adoption of various other outcome-based quality measures in those specific settings. The final specifications for this cross-setting measure are posted on the CMS Web

[336] For example, in the NQF-endorsed process measure Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (long stay) (NQF#0686) for which we are the steward, resident-level limited covariates (Frequent bowel incontinence, or always incontinent on prior assessment; and Pressure ulcers at stages II, III, or IV on prior assessment) are used in a logistic regression model to calculate a resident-level expected quality measure score.

site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*. In the cross-setting process measure, there is a common core subset of function items that will allow tracking of patients' functional status across settings that are identical across the settings. We have updated the specifications to include a table indicating which functional assessment items are used in the cross-setting process measure, as well as the setting-specific outcome measures.

We appreciate the commenters' views pertaining to the differences in the function quality measure denominators by payer type across the IRF, SNF and LTCH settings. We also appreciate the commenters' suggested expansion of the population used to calculate all measures to include payer sources beyond Medicare PPS and agree that quality measures that include all persons treated in a facility are better able to capture the health outcomes of that facility's patients or residents, and that quality reporting on all patients or residents is a worthy goal. We believe that quality care is best represented through the inclusion of all patient data regardless of payer source and we agree that consistency in the data would reduce confusion in data interpretation and enable a more comprehensive evaluation of quality. We appreciate the commenter's concerns and, although we had not proposed all payer data collection through this current rulemaking, we will take into consideration the expansion of the LTCH QRP to include all payer sources through future rulemaking.

Finally, we are clarifying that while the IMPACT Act requires the enablement of interoperability through the use of standardized data, there will be instances whereby some provider types may need more or less standardized items than other provider types.

Comment: One commenter was concerned that no data was provided clearly linking improved outcomes to this process measure.

Response: The NQF requirement for endorsing process measures is that the process should be evidence-based, such as processes that are recommended in clinical practice guidelines. As part of the NQF process, we submitted to the NQF several such clinical practice guidelines [337] [338] [339] to support this measure and referenced another cross-cutting clinical practice guideline in the proposed rule. Due to this, we believe that there is evidence that this is a best practice based on several clinical practice guidelines. The clinical practice guideline Assessment of Physical Function[340] recommends that clinicians should document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge and establishing a functional goal for discharge as part of the care plan (that is, treatment plan) is an important aspect of patient/resident care for all of these PAC providers.

Comment: One commenter suggested that the PAC PRD data was collected only by therapists, and expressed concern that the items had not been tested using other care providers. In addition, this commenter had specific questions about scoring different assessments during the time frame proposed. The commenter also asked CMS to specify which clinicians may complete function items in Section GG.

Response: We wish to clarify that during the PAC PRD, data were collected by clinicians from many different disciplines, including nurses, occupational therapists (OTs), physical therapists (PTs), speech-language pathologists (SLPs), and registered nurses (RNs). The reliability testing included testing by discipline, as well as testing by setting.

The items were developed with the input with who would be performing the assessments, which included OTs, PTs, SLPs, and RNs. Regarding the questions about scoring assessments and staff that will be trained to complete functional assessments, we have historically provided training for providers. As we prepare for this type of training, we have this type of information available to the public to increase transparency and readiness.

Comment: Several commenters encouraged CMS to provide standardized education to all providers that will be using the CARE items throughout the transition period. In addition, several commenters raised concerns about the scoring of Section GG of the LTCH CARE Data Set, and who would be trained to collect the items in Section GG, and how ''usual performance'' in the proposed Section GG is defined. The commenters also asked for CMS' transparency through this process.

Response: We understand the importance of education and have worked in the past with public outreach including training sessions, training manuals, Webinars, open door forums, help desk support, and a Web site that hosts training information (*http://www.youtube.com/user/CMSHHSgov*). We plan to conduct such activities for the new items.

Comment: Several commenters encouraged CMS to continue ongoing stakeholder engagement as the function quality measures evolve and as new function measures, including additional concepts for cognition and mobility, are considered.

Response: We thank the commenters for the suggestion, and appreciate the continued involvement of stakeholders in all phases of measure development and implementation. We will continue to engage stakeholders as we implement the IMPACT Act.

Comment: One commenter expressed concern about items related to cognitive functioning, including communication and swallowing, being included only as risk-adjustors. The commenter recommended that CMS engage stakeholders to develop future outcome measures in the area of cognitive function.

Response: We are clarifying that the proposed LTCH process measure, an Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), is not risk adjusted. We agree that future development of outcome measurement should include other areas of function, such as cognition, expression, and swallowing. We will continue to engage stakeholders as we develop quality measures to meet the requirements of the IMPACT Act.

After consideration of the public comments we received, we are finalizing our proposal to adopt the application of the Percent of LTCH Patients with an Admission and

[337] Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103. Retrieved from *http://www.guideline.gov/content.aspx?id=43918*.

[338] Centre for Clinical Practice at NICE (UK). (2009). Rehabilitation after critical illness (NICE Clinical Guidelines No. 83). Retrieved from *http://www.nice.org.uk/guidance/CG83*.

[339] Balas MC, Casey CM, Happ MB. Comprehensive assessment and management of the critically ill. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 600–27. Retrieved from *http://www.guideline.gov/content.aspx?id=43919*.

[340] Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103. Retrieved from *http://www.guideline.gov/content.aspx?id=43918*.

Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) measure for the FY 2018 payment determination and subsequent years to fulfill the requirements of the IMPACT Act.

7. LTCH QRP Quality Measures for the FY 2019 Payment Determination and Subsequent Years

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24605), we did not propose any additional LTCH QRP quality measures for the FY 2019 payment determination and subsequent years. Under our policy discussed in section VIII.C.3. of the preamble of this final rule, we will retain all previously adopted quality measures and, the additional finalized measures in this FY 2016 IPPS/LTCH PPS final rule for the FY 2019 payment determination and subsequent years.

8. LTCH QRP Quality Measures and Concepts Under Consideration for Future Years

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24605), we invited public comments on importance, relevance, appropriateness, and applicability of each of the quality measures and quality measure concepts listed in the table below for future years in the LTCH QRP. Specifically, we invited public comments regarding the clinical importance to the LTCH patient population and the feasibility of data collection and implementation in the LTCH setting for these measures and measure concepts in order to inform and improve quality of care delivered to LTCH patients.

FUTURE MEASURES AND MEASURE CONCEPTS UNDER CONSIDERATION FOR THE LTCH QRP

National Quality Strategy (NQS) Priority: Patient Safety
Ventilator Weaning (Liberation) Rate
Compliance with ventilator process Elements during LTCH Stay
Venous Thromboembolism Prophylaxis
Medication Reconciliation *
NQS Priority: Effective Communication and Coordination of Care
Transfer of health information and care preferences when an individual transitions *
All-Condition Risk-Adjusted Potentially Preventable Hospital Readmission Rate *
NQS Priority: Patient- and Caregiver-Centered Care
Discharge to community *
Patient Experience of Care
Percent of Patients with Moderate to Severe Pain
Advance Care Plan
NQS Priority: Affordable Care
Medicare Spending per Beneficiary *

* Indicates that this is a cross-setting measure domain listed in the IMPACT Act.

Comment: One commenter supported most of the measures and measure concepts under consideration for the LTCH QRP, as they are applicable to an LTCH population, clinically important, and potentially feasible to collect.

Response: We appreciate the commenter's support of these future measures and measure concepts under consideration.

Comment: Some commenters provided recommendations about the Ventilator Weaning (Liberation) Rate measure. One commenter urged CMS to utilize the TEP in fully testing the ventilator weaning measure before it is considered for inclusion in the LTCH QRP. Another commenter stated that this measure is an appropriate quality measure for LTCHs; however, it will be important to carefully specify the inclusion and exclusion criteria and appropriately risk adjust. This commenter also noted examples where patients enter an LTCH without an expectation of successfully weaning, such as patients with spinal cord injuries or ALS, and stated that, for some patients, terminal weaning is an appropriate outcome.

Response: We appreciate the commenters' support and suggestions for this measure. We will take these into consideration to inform our ongoing measure development efforts. Our measure development contractor, RTI International, will continue to engage members of a TEP originally convened in April 2014 through a national call for TEP members. This TEP is providing ongoing advisement to our measure development contractor on all aspects, including this measure's denominator, numerator, inclusion and exclusion criteria, risk adjustment, as well as development and feasibility of data elements.

Comment: One commenter expressed concerns that CMS is proposing Discharge to the Community, Medicare Spending per Beneficiary (MSPB), and All-Condition Risk-Adjusted Potentially Preventable Hospital Readmission Rate Hospital Readmissions as cross-cutting measures to fulfill the requirements of the IMPACT Act.

Response: We are clarifying that we did not propose these measures in the FY 2016 IPPS/LTCH PPS proposed rule. Rather, we included these measures and measure concepts as measures under consideration and measures under development for future years of the LTCH QRP to fulfill the requirements of the IMPACT Act. We and our measure development contractors are in the early stages of development of these quality measures to meet the requirements of the IMPACT Act.

Comment: One commenter expressed concern for the All-Condition Risk-Adjusted Potentially Preventable Hospital Readmission Rate since LTCH patients are at a much higher severity level and, thus, have higher risk of readmission than other PAC settings. The commenter stated that to make valid comparison across settings, it is important to adequately risk adjust this measure. The commenter noted that CMS currently uses diagnosis information on claims to risk adjust its readmission measures, and the ability of claims data to fully capture the severity of the patient populations treated by LTCHs is limited as demonstrated by a number of studies showing the importance of controlling for risk factors that do not appear on the claim when assessing the performance of LTCHs relative to other providers. In conclusion, the commenter noted that it is important to assess the value of incorporating assessment data for risk adjustment before using this measure to assess performance across settings.

Response: We thank the commenter for its comments and suggestions. We agree with these comments and agree it is important to carefully examine and identify risk factors for the All-

Condition Risk-Adjusted Potentially Preventable Hospital Readmission Rate measure before using this measure to assess and report on performance of LTCHs as part of LTCH QRP as well as for valid and reliable comparisons across settings. We will take these comments under advisement as we develop the All-Condition Risk-Adjusted Potentially Preventable Hospital Readmission Rate measure. We will also seek input from a panel of experts to inform our identification of risk factors and approach to risk adjustment for this measure. We agree with the commenter's suggestion that we consider differences LTCH and other providers, and the implications of those differences on measure specification and intend to do so in our development of this measure, as well as for all future measures, for the LTCH QRP.

Comment: One commenter expressed concerns regarding the Discharge to Community measure, particularly if used to compare PAC settings. The commenter noted that many LTCH patients, given their severity and conditions, are not appropriate for returning to the community upon discharge but are, appropriately, transferred to a lower-level of care (such as a Skilled Nursing Facility). The commenter recommended that sufficient risk adjustment approaches that would standardize adequately for patient differences across settings to permit fair comparisons on this quality measure across PAC settings need to be developed. The commenter stated that, at a minimum, this measure needs to be carefully assessed for validity and reliability in all PAC settings. The commenter stated that risk adjustment should include not only information available from claims data but also information from assessment data, including functional status, and that it may be necessary to stratify patients based on condition and/or functional status rather than grouping all patients together. The commenter recommended that CMS move cautiously in developing and adopting a discharge to the community measure that covers all PAC settings.

This commenter also commented on the MSPB measure. The commenter expressed similar concerns on this measure as with the hospital readmission measure and discharge to the community measure. In addition, the commenter noted that a 30-days post-discharge episode is not sufficiently long to capture the consequences of receiving care in an LTCH. The commenter noted the importance of assessing an alternative definition of MSPB and the value of incorporating assessment data for risk adjustment before using this measure to assess performance across settings.

Response: We thank the commenter for the detailed recommendations to inform our efforts to develop a valid, reliable, and usable measure of Discharge to Community and Medicare Spending per Beneficiary measure for PAC settings. We agree with the commenter's suggestion that we consider differences across PAC providers, and the implications of those differences on measure specifications and intend to do so in our development of these two measures, as well as for all future measures. We are at early stages of development of these measures and appreciate this commenter's timely inputs to inform our measure development processes. We remain committed to employing an environmental scan and engaging a TEP to identify findings from prior work for the LTCH setting as well as other PAC settings to inform our development of resource use measures, including the development of the MSPB measure and the Discharge to Community measure, for the LTCH setting and other PAC settings in order to meet the requirements of the IMPACT Act. We also remain committed to following the same rigorous measure development process as the other publicly reported measures included in our current Quality Reporting Programs and will involve extensive input by stakeholders and clinical experts as well as follow the same scientific approach to evaluate this measure prior to public reporting to ensure meaningful and valid comparisons across settings.

Comment: One commenter encouraged CMS to consider implementing palliative care-related measures into the LTCH QRP. The commenter suggested that priority should be given to NQF-endorsed palliative care measures that address pain, dyspnea, patient values and goals, and care direction and coordination. The commenter noted that existing measures should be revisited and expanded to include a broader population of sick patients across healthcare settings. The commenter also urged CMS to drive the development of patient-centered measures for shared accountability for care coordination through transitions, advance care planning and goals of care conversations and structural/process measures related to access to quality palliative care, utilization of quality of palliative care, and integration/continuity of palliative care across settings.

Another commenter recommended the implementation of a malnutrition quality measure because malnutrition is a patient safety issue which can negatively impact patient outcomes across healthcare settings. The commenter noted that early identification of patients at-risk for malnutrition, prompt nutrition intervention, and implementation of a care plan for patients diagnosed as malnourished or at-risk for malnutrition are critical to improve outcomes and patient safety by reducing complications, such as infections, falls, and pressure ulcers.

Response: We thank the commenters for the comments and suggestions and will take these into consideration as we develop future measures for the LTCH QRP and other quality reporting programs. We agree with the commenter's recommendation and rationale for consideration of malnutrition is an important quality measure concept for the LTCH setting. Further, we agree that palliative care-related measures could be considered for the LTCH QRP and will examine the applicability, usability, feasibility, validity and reliability of existing quality measures and need for new measures of palliative care for the LTCH QRP.

Comment: One commenter noted additional areas of function that are key to patients, including cognition, communication, and swallowing. The commenter encouraged CMS to consider cognition and expressive and receptive language and swallowing as items of function, and offered its expertise to CMS for discussions and to develop goals. The commenter recommended that CMS engage stakeholders to develop future outcome measures in the area of cognitive function.

Response: We thank the commenter for its suggestions and expertise to inform our measure development efforts. We agree that future development of outcome measures should include other areas of function, such as cognition, communication, and swallowing, are important aspects of functional assessment and improvement for patients who receive care in PAC settings, including LTCHs. We will continue to engage stakeholders as we develop and implement quality measures to meet the requirements of the IMPACT Act. We will take these quality measure concepts into consideration for future measure selections and measure development activities for the LTCH QRP.

We thank the commenters for their views and we will consider them as we develop future measures and future proposals.

9. Form, Manner, and Timing of Quality Data Submission for the FY 2016 Payment Determination and Subsequent Years

a. Background

Section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit to the Secretary data on quality measures specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires that, for the fiscal year beginning on the specified application date, as defined in section 1899B of the Act, and each subsequent year, each LTCH submit to the Secretary data on measures specified by the Secretary under section 1899B of the Act. The data required under section 1886(m)(5)(C) and (F) of the Act must be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(m)(5)(A)(i) of the Act, for any LTCH that does not submit data in accordance with section 1886(m)(5)(C) of the Act with respect to a given rate year, any annual update to the standard Federal rate for discharges for the LTCH during the rate year must be reduced by 2 percentage points.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50857 through 50861 and 50878 through 50881), we finalized the data submission timelines and submission deadlines for measures for the FY 2016 and FY 2017 payment determinations. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a more detailed discussion of these timelines and deadlines. Specifically, we refer readers to the table at 78 FR 50878 of the FY 2014 IPPS/LTCH PPS final rule for the data collection period and submission deadlines for the FY 2016 payment determination and the tables at 78 FR 50881 of that final rule for the data collection timelines and submission deadlines for the FY 2017 payment determination.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50307 through 50311), we:

- Revised the previously adopted data collection period and submission deadlines for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2016 payment determination and subsequent years;
- Adopted data submission mechanisms for the FY 2018 payment determination and subsequent years for new LTCH QRP quality measures and for revisions to previously adopted quality measures;
- Adopted data collection periods and submission deadlines for certain measures under the LTCH QRP for the FY 2018 payment determination;
- Revised data collection timelines and submission deadlines for the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure for the FY 2018 payment determination and subsequent years; and
- Adopted data collection timelines and submission deadlines under the LTCH QRP for the FY 2019 payment determination and subsequent years.

b. Timing for New LTCHs to Begin Reporting Data to CMS for the FY 2017 Payment Determination and Subsequent Years

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24606), beginning with the FY 2017 payment determination, we proposed that a new LTCH be required to begin reporting quality data under the LTCH QRP by no later than the first day of the calendar quarter subsequent to 30 days after the date on its (CCN) notification letter. For example, if an LTCH's CCN notification letter is dated March 15, then the LTCH would be required to begin reporting quality data to CMS beginning on July 1 (March 15 + 30 days = April 14 (quarter 2)). The LTCH would be required to begin collecting quality data on the first day of the quarter subsequent to quarter 2, which is quarter 3, or July 1. The collection of quality data would begin on the first day of the calendar year quarter identified as the start date, and would include all LTCH admissions and subsequent discharges beginning on, and subsequent to, that day; however, submission of quality data would be required by previously finalized or newly proposed quarterly deadlines.

In order to determine which quality measure data an LTCH would need to begin submitting, we refer readers to section VIII.C.9.c. of the preamble of this final rule, below, as it will vary depending upon the timing of the CY quarter identified as a start date. We also proposed to codify this requirement for the timing of new LTCHs to begin reporting for purposes of the LTCH QRP at new proposed § 412.560(a). We invited public comment on our proposals to add and codify this requirement for the timing of new LTCHs to begin reporting for purposes of the LTCH QRP.

We did not receive any public comments on these proposals. Therefore, we are finalizing our proposals regarding the timing for new LTCHs to being reporting quality data under the LTCH QRP for the FY 2017 payment determination and subsequent years.

c. Revisions to Previously Adopted Data Submission Timelines Under the LTCH QRP for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years and Proposed Data Collection and Data Submission Timelines for Quality Measures Finalized in This Final Rule

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53637), we finalized new quarterly quality data submission deadlines for LTCHs. We contracted the deadlines from the original 4.5-months post-CY quarter submission deadlines, to 1.5 months (approximately 45 days) deadlines. In order to align the data submission and correction deadlines with the IRF QRP and Hospital IQR Program as we near public reporting, and to meet the requirements of the IMPACT Act, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24606 through 24608), we proposed to revise the data submission and correction deadlines for quality measures previously adopted for the LTCH QRP for the FY 2017 and FY 2018 payment determinations and subsequent years.

We proposed to adopt new deadlines that allow 4.5 months (approximately 135 days) after the end of each calendar year quarter for quality data submission, beginning with quarter 4 2015 (October 2015 through December 2015). Under this new policy, LTCHs will have approximately 135 days following the end of each calendar year quarter, during which to submit, review, and correct their quality data for that CY quarter. We also proposed data collection and data submission timelines for quality measures that we proposed for the FY 2018 payment determination and subsequent years. Further, for the measures proposed in the proposed rule, and finalized within this final rule—Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), the application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), and the application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015)—we proposed that the data collection and data submission timelines align with the proposed data collection and data submission timelines for each respective measure starting with April 1, 2016. Because the All-Cause Unplanned Readmission Measure for 30 Days Post-

Discharge from LTCHs (NQF #2512) is a Medicare FFS claims-based measure, the data collection and submission timelines are not applicable to this measure. In addition, we note that upon further consideration of how this policy affects the required reporting of quality measures under the LTCH QRP, that the application of this extended deadline to the measure Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), is not feasible. Data for this measure is only collected between the dates of October 1st and March 31st, and is only required to be submitted to CMS via the CDC's NHSN once per year. Allowing the extended deadline of 135 days beyond the end of the data collection period for this measure would not allow the application of the appropriate FY APU determination, as previously finalized. Because of this, we are finalizing this policy with the exception of its application to the measures Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

The tables below present the data collection period and data submission timelines for quality measures affecting the FY 2017 payment determination, as well as the revisions to the data collection period and data submission timelines for quality measures for the FY 2018 payment determination and subsequent years.

We would like to note that the tables below, as displayed in the proposed rule, contained technical errors with respect to the measure Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). In the FY 2016 IPPS/LTCH PPS proposed rule, we accidentally omitted this measure from the first table below, which refers to measures affecting the FY 2017 payment determination. We have added this measure (NQF #0431) back to the first table below, including the correct submission deadlines, as they related to our decision to refrain from applying this policy to this measure. In the proposed rule we also listed the data submission deadlines as they pertain to this same measure (NQF #0431) related to the FY 2018 payment determination and subsequent years, but note that the data submission deadlines in table two have been corrected to reflect our decision to finalize this policy with exception of this measure.

DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR QUALITY MEASURES AFFECTING THE FY 2017 PAYMENT DETERMINATION

Quality measure	NQF ID#	Submission method	Data collection period	Proposed data submission deadlines	APU Determination affected
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay).	#0678	LTCH CARE Data Set/QIES ASAP system.			
NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	#0138				
NHSN Central-Line Associated Bloodstream Infections (CLABSI) Outcome Measure.	#0139	CDC NHSN	Q1: 1/1/15–3/31/15 .. Q2: 4/1/15–6/30/15 .. Q3: 7/1/15–9/30/15 .. Q4: 10/01/15–12/31/15.	5/15/15 (Q1) ..... 8/15/15 (Q2) ..... 11/15/15 (Q3) ..... Finalized in this final rule: 5/15/16 (Q4).	FY 2017.
NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	#1716				
NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	#1717				
			10/1/15 (or when vaccine becomes available)–3/31/16.	5/15/16 **	FY 2017.**
Influenza Vaccination Coverage Among Healthcare Personnel.	#0431	CDC NHSN			
			10/1 (or when vaccine becomes available)–3/31.	5/15 for subsequent years.	Subsequent Years.
All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals*.	#2512	Medicare FFS Claims Data.	N/A	N/A	For future public reporting.

* This measure will not be used in determining compliance for the LTCH QRP because it is a claims-based measure and LTCHs do not report additional data to CMS.

** We are finalizing the proposed policy to extend the current quarterly data submission deadlines from 45 days to 135 days with the exception of this quality measure. We refer readers to section VIII.C.9.c. of the preamble of this final rule for further information.

DETAILS ON DATA COLLECTION AND SUBMISSION TIMELINE FOR QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	NQF ID#	Submission method	Data collection period	Proposed data submission deadlines	APU Determination affected
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay).	#0678	LTCH CARE Data Set/QIES ASAP system.	Q1: 1/1/16–3/31/16 .. Q2: 4/1/16–6/30/16 .. Q3: 7/1/16–9/30/16 .. Q4: 10/01/16–12/31/16.	8/15/16 (Q1) ..... 11/15/16 (Q2) ..... 2/15/17 (Q3) 5/15/17 (Q4)	FY 2018 and Subsequent Years.
NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	#0138	CDC NHSN	Quarterly for each subsequent calendar year.		
NHSN Central-Line Associated Bloodstream Infections (CLABSI) Outcome Measure.	#0139			Approximately 135 days after the end of each quarter.	
NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	#1716				
NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	#1717				
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.	#0680	LTCH CARE Data Set/QIES ASAP system.	10/1/15–12/31/15 ..... 1/1/16–3/31/16 ..... 10/1–12/31 ..... 1/1–3/31 for subsequent years.	5/15/16 ..... 8/15/16 ..... 5/15 ..... 8/15 for subsequent years.	FY 2018 Subsequent Years.
Influenza Vaccination Coverage Among Healthcare Personnel.	#0431	CDC NHSN	10/1/16 (or when vaccine becomes available)–3/31/17. 10/1 (or when vaccine becomes available)–3/31.	5/15/17** ..... 5/15 for subsequent years.	FY 2018** Subsequent Years.
All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long Term Care Hospitals*.	#2512	Medicare FFS Claims Data.	N/A	N/A	For future public reporting.
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).	#0674				
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	#2631 (endorsed on 07/23/2015)	LTCH CARE Data Set/QIES ASAP system.	4/1/16–6/30/16 ..... 7/1/16–9/30/16 ..... 10/1/16–12/31/16	11/15/16 (Q2) ..... 2/15/17 (Q3) 5/15/17 (Q4)	FY 2018 Subsequent Years.
Functional Status Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support.	#2632 (endorsed on 7/23/2015)		Quarterly for each subsequent calendar year.	Quarterly approximately 135 days after the end of each quarter for subsequent years.	
			1/1/16–3/31/16 ..... 4/1/16–6/30/16 ..... 7/1/16–9/30/16 ..... 10/1/16–12/31/16	8/15/16 (Q1) ..... 11/15/16 (Q2) ..... 2/15/17 (Q3) 5/15/17 (Q4)	FY 2018 Subsequent Years.
Ventilator Associated Event	N/A	CDC NHSN.	Quarterly for each subsequent calendar year.	Quarterly approximately 135 days after the end of each quarter for each subsequent year.	
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	#2631 (endorsed on 7/23/2015)	LTCH CARE Data Set/QIES ASAP system.	4/1/16–6/30/16 ..... 7/1/16–9/30/16 ..... 10/1/16–12/31/16	11/15/16 (Q2) ..... 2/15/17 (Q3) 5/15/17 (Q4)	FY 2018.

DETAILS ON DATA COLLECTION AND SUBMISSION TIMELINE FOR QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Quality measure	NQF ID#	Submission method	Data collection period	Proposed data submission deadlines	APU Determination affected
			Quarterly for each subsequent calendar year.	Quarterly approximately 135 days after the end of each quarter for subsequent years.	Subsequent Years.

* This measure will not be used in determining compliance for the LTCH QRP because it is a claims-based measure and LTCHs do not report additional data to CMS.

** We are finalizing the proposed policy to extend the current quarterly data submission deadlines from 45 days to 135 days with the exception of this quality measure. We refer readers to section VIII.C.9.c.of the preamble of this final rule for further information.

We invited public comments on our proposals.

Comment: Several commenters supported the proposal to extend the data submission timeframes for the LTCH QRP measures from 45 days (1.5 months) to 4.5 months (approximately 135 days) from the end of a calendar year quarter for the FY 2017 and FY 2018 payment determinations and subsequent years. The commenters agreed that this change would align data submission and correction deadlines with other quality reporting programs and facilitate public reporting.

Response: We appreciate commenters' support of this proposal.

After consideration of the public comments we received, we are finalizing our proposal to revise the data submission and correction timelines for the FY 2017 and FY 2018 payment determinations and subsequent years for all measures except the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). For the reasons stated above, for the measure Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), we are retaining previously finalized data submission timelines for the FY 2017 and FY 2018 payment determinations and subsequent years. We refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50858) for data submission deadlines for FY 2017 payment determination for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). We refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50882 through 50883) for data submission deadlines for FY 2018 payment determination for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). We refer readers to FY 2015 IPPS/LTCH PPS final rule ((79 FR 50311)) for data submission deadlines for FY 2019 payment determination for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

10. Previously Adopted LTCH QRP Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314), we finalized specific LTCH QRP thresholds for completeness of LTCH data submissions. To ensure that LTCHs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning with the FY 2016 payment determination and for each subsequent year, LTCHs must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of quality measures data collected using the LTCH CARE Data Set and submitted through the QIES ASAP system; and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN.

In addition, we stated that we would apply the same thresholds to all measures adopted as the LTCH QRP expands and LTCHs report data on the finalized measure sets. That is, as we finalize new measures through the regulatory process, LTCHs will be held accountable for meeting the previously finalized data completion threshold requirements for each measure until such time that updated threshold requirements are proposed and finalized through a subsequent regulatory cycle.

Further, we finalized the requirement that a LTCH must meet or exceed both thresholds in order to avoid receiving a 2-percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24608), we did not propose any changes to these policies. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314) for a detailed discussion of the finalized data completion requirements of the LTCH QRP.

11. Future LTCH QRP Data Validation Process

Historically, we have built consistency and internal validation checks into our data submission specifications to ensure that the data elements of the LTCH CARE Data Set assessments conform to requirements such as proper format and facility information. These internal consistency checks are automated and occur during the LTCH data entry and submission process, and help ensure the integrity of the data submitted by LTCHs by rejecting submissions or issuing warnings when LTCH data contain logical inconsistencies. These internal consistency checks are referred to as ''system edits'' and are further outlined in the LTCH Data Submission Specifications version 1.01, which are available for download on the LTCH Quality Reporting Technical Information Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by sections 1886(m)(5)(E) and 1899B(g) of the Act. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28275 through 28276), we proposed, for the FY 2016 payment determination and subsequent years, to validate the data elements submitted to CMS for quality purposes. We also proposed policies regarding the application of the 2-percentage point reduction for LTCHs that failed to meet the data accuracy threshold.

However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50314 through 50316), we decided to further explore suggestions from commenters before finalizing the LTCH data validation process that we proposed. Therefore, we did not finalize the data validation proposals.

At this time, we are continuing to explore data accuracy validation methods and threshold policies that will limit the amount of burden and cost to LTCHs, while allowing us to establish estimations of the accuracy of LTCH QRP data. Therefore, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24608), we did not propose any new policies related to data accuracy validation, but we plan to do so in future rulemaking cycles.

While we did not solicit comments specifically regarding our policies related to data accuracy validation, we received a comment, which we summarize and respond to below.

Comment: One commenter supported CMS' decision to continue to explore data validation methods that take provider burden into account.

Response: We thank the commenter for its support. We will take this comment into consideration in future rulemaking.

12. Public Display of Quality Measure Data for the LTCH QRP

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public. In so doing, the Secretary must ensure that LTCHs have the opportunity to review any such data with respect to the LTCH prior to its release to the public. Section 1899B(g) of the Act requires the Secretary to establish procedures for making available to the public information regarding the performance of individual PAC providers with respect to the measures required under section 1899B of the Act beginning not later than 2 years after the applicable specified application date. The procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act for similar purposes, that each PAC provider has the opportunity to review and submit corrections to the data and information that are to be made public with respect to the PAC provider prior to such data being made public.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24608 through 24610), we proposed to display performance data related to the LTCH QRP quality measures, as applicable, required by the LTCH QRP by fall 2016 on a CMS Web site, such as the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov*), after a 30-day preview period. Additional information about preview report content and delivery will be announced on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html.* LTCHs would be notified via CMS listservs, CMS mass emails and memorandums, LTCH QRP Web site announcements and Medicare Learning Network announcements regarding the release of preview reports, as well as the timing of the posting of provider data.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their hospital to discuss the quality of care provided to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish. As we have done on some of the other CMS *Compare* Web sites, we will, at some point in the future, report public data using a quality rating system that gives each LTCH a rating of between one and five stars. Initially, however, we will not use the 5-star methodology, until such time that we are publicly reporting a sufficient number of quality metrics to allow for variation and the differentiation among LTCHs using this methodology. Decisions regarding how the rating system will determine an LTCH's star rating and methods used for calculations, as well as a proposed timeline for implementation, will be announced via regular LTCH communication channels, including listening sessions, memos, email notification, provider association calls, open door forums, and Web postings.

The initial display of information would contain performance data on four quality measures: (1) NHSN CAUTI Outcome Measure (NQF #0138); (2) NHSN CLABSI Outcome Measure (NQF #0139); (3) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678); and (4) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). We proposed to publicly report data beginning with data collected on these measures for the first quarter of 2015, or discharges beginning January 1, 2015, with exception of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). Rates would be displayed based on four (4) rolling quarters of data and would use discharges from January 1, 2015 through December 31, 2015 (CY 2015), for calculation, with exception of the measure All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). With respect to LTCH performance related to the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), proposed to publicly report readmission rates beginning with Medicare FFS claims data for patient discharges starting with January 1, 2013. Readmission rates will be calculated using Medicare FFS claims data for two consecutive years (for example, readmission rates will be calculated using Medicare FFS claims data for January 1, 2013 through December 31, 2014 (CY 2013 and CY 2014)) and displayed on a calendar year basis.

Calculations for the CAUTI and CLABSI measures adjust for differences in the characteristics of hospitals and patients using a Standardized Infection Ratio (SIR). The SIR is a summary measure that takes into account differences in the types of patients that a hospital treats. The SIR may take into account the type of patient care location, laboratory methods, hospital affiliation with a medical school, bed size of the hospital, patient age, and American Society of Anesthesiologists' classification of physical health. It compares the actual number of HAIs in a facility or State to a national benchmark based on previous years of reported data and adjusts the data based on several factors. A confidence interval with a lower and upper limit is displayed around each SIR to indicate that there is a high degree of confidence that the true value of the SIR lies within that interval. A SIR with a lower limit that is greater than 1.0 means that there were more HAIs in a facility or State than were predicted, and the facility is classified as ''Worse than the U.S. National Benchmark.'' If the SIR has an upper limit that is less than 1, the facility had fewer HAIs than were predicted and is classified as ''Better than the U.S. National Benchmark.'' If the confidence interval includes the value of 1, there is no statistical difference between the actual number of HAIs and the number predicted, and the facility is classified as ''No Different than U.S. National Benchmark.'' If the number of predicted infections is less than 1, the SIR and confidence interval cannot be calculated.

Calculations for the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678) would be risk-adjusted. Resident- or patient-level covariate risk adjustment is performed. Resident- or patient-level covariates are used in a logistic regression model to calculate a resident- or patient-level expected quality measure (QM) score (the probability that the resident or patient will evidence the outcome, given the presence or absence of patient

characteristics measured by the covariates). Then, an average of all resident- or patient-level expected QM scores for the facility is calculated to create a facility-level expected QM score. The final facility-level adjusted QM score is based on a calculation which combines the facility-level expected score and the facility level observed score. Additional information about the covariates can be found at: *http://www.qualityforum.org/QPS/0678*.

Finally, calculation for performance on the measure All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) will also be risk-adjusted. The risk adjustment methodology is available, along with the specifications for this measure, on our LTCH Quality Reporting Measures Information Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We are currently developing reports that will allow providers to view the data that is submitted to CMS via the QIES ASAP system and the CDC's NHSN (Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), the NHSN CAUTI Outcome Measure (NQF #0138) and the NHSN CLABSI Outcome Measure (NQF #0139), respectively). These reports, although not initially, will also include provider performance on any currently reported quality measure that is calculated based on CMS claims data that we plan on publicly reporting (All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512)). Although real time results will not be available, the report will refresh all of the data submitted at least once a month.

We proposed a process to give providers an opportunity to review and correct data submitted to the QIES ASAP system or to the CDC's NHSN by utilizing that report. Under this proposed process, providers would to have the opportunity to review and correct data they submit on all assessment-based measures. Providers can begin submitting data on the first admission of any reporting quarter. Providers are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before the quarterly submission deadline. The data would be populated into reports that are updated at least once a month with all data that have been submitted. That report would contain the provider's performance on each measure calculated based on assessment submissions to the QIES ASAP system or CDC NHSN. We believe that the submission deadline timeframe, which we proposed in the proposed rule to extend from the current 1.5 month policy to 4.5 months beyond the end of each calendar year quarter, is sufficient time for providers to be able to submit, review data, make corrections to the data, and view their data. We proposed that once the provider has an opportunity to review and correct quarterly data related to measures submitted via the QIES ASAP system or CDC NHSN, we would consider the provider to have been given the opportunity to review and correct this data. We would not allow patient-level data correction after the submission deadline or for previous years. This is because we must set a deadline to ensure timely computation of measure rates and payment adjustment factors. Before we display this information, providers will be permitted 30 days to review their information as recorded in the QIES ASAP system or CDC NHSN.

We invited public comment on these proposals.

Comment: Several commenters supported the proposal to publicly report LTCH quality data beginning in fall 2016, although some urged that CMS allow for correction of LTCH data during the 30-day preview period. Other commenters supported the proposal but recommended that CMS set up a separate *LTCH Compare* Web site so that LTCHs are only compared to other LTCHs and the public can make an informed comparison without unnecessary confusion.

Response: We thank the commenters for their comments and support of our proposal to publicly report LTCH quality data beginning in fall 2016. In our proposal we note that we have extended the post-calendar year (CY) quarter submission deadlines from the current 45 days beyond the end of each quarter to 135 days beyond the end of each quarter. We believe that this timeframe allows LTCHs sufficient time to submit, review, and correct their data prior to public reporting of that data. We have designed and will be issuing provider reports immediately following the end of each CY quarter, which will allow LTCHs to see the data they have submitted to CMS to date. LTCHs will then have the additional 135 days beyond the end of each CY quarter to correct any data they feel has been submitted in error, or is missing. While many LTCHs use the current post-CY quarter timeframe as an extended submission timeframe, the original intent of the post-CY quarter timeframe was to allow LTCHs to review and correct any data they had submitted for that particular CY quarter.

We have continually urged LTCHs to submit their quality data as soon as possible, thus allowing ample time for review and correction. We will not allow any correction of patient-level data during the 30-day preview period. We will issue a preview report at the beginning of this period that contains provider performance data, and LTCHs will have 30 days during which to refute any quality measure calculations they feel have been made in error. This policy aligns with that of the Hospital IQR Program and the IRF QRP. Allowing for patient level data correction at this time would have the effect of negating our data submission deadlines.

Regarding the comment that we should develop a separate *LTCH Compare* Web site, as opposed to posting LTCH QRP performance data on *Hospital Compare,* we would like to clarify that should we choose to post this data on *Hospital Compare,* it would be under its own separate tab/Web page, and would be clearly separate from acute care hospital data. Because we have not made any final decision regarding this issue, we will take this comment into consideration as we move forward with the development of the Web site.

After consideration of the public comments we received, we are finalizing our proposals to display performance data for the quality beginning in fall 2016 on a CMS Web site, such as the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov*), after a 30-day preview period, and to give providers an opportunity to review and correct data submitted to the QIES ASAP system or to the CDC NHSN.

In addition to our proposal to publicly display LTCH performance data on the required quality measures under the LTCH QRP, we also proposed to publish a list of LTCHs that successfully meet the reporting requirements for the applicable payment determination on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*. We proposed to update the list after reconsideration requests are processed on an annual basis. We proposed to codify the policy to publish a list of compliant LTCHs on the LTCH QRP Web site at new proposed § 412.560(d)(3).

We invited public comment on these proposals.

We did not receive any public comments on our proposals to publish a list of LTCHs that successfully meet

the reporting requirements for each applicable payment determination on the LTCH QRP Web site, update the list after reconsideration requests are processed on an annual basis, and codify the policy to publish a list of compliant LTCHs on the LTCH QRP Web site at new proposed § 412.560(d)(3). Therefore, we are finalizing these proposals.

13. Previously Adopted and Finalized LTCH QRP Reconsideration and Appeals Procedures for the FY 2017 Payment Determination and Subsequent Years

At the conclusion of each fiscal year reporting cycle, we review the data received from each LTCH to determine if the LTCH met the reporting requirements set forth for that reporting cycle. LTCHs that are found to be noncompliant will receive a reduction in the amount of 2 percentage points to their annual payment update for the applicable fiscal year. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317 through 50318), we described and adopted an updated process that enables an LTCH to request a reconsideration of our initial noncompliance decision in the event that an LTCH believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its annual payment due to noncompliance with the LTCH QRP reporting requirements for a given reporting period.

We are clarifying that any LTCH that wishes to submit a reconsideration request must do so by submitting an email to CMS containing all of the requirements listed on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Exception-and-Extension.html*. Email sent to *LTCHQRPReconsiderations@cms.hhs.gov* is the only form of submission that will be accepted from an LTCH provider requesting reconsideration. Any reconsideration requests received through another channel, including the U.S. Postal Service (USPS) or telephone, will not be considered as a valid reconsideration request.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24610 through 24611), we proposed to continue using the LTCH QRP reconsideration and appeals procedures that were adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317 through 50318) and that have been posted on the LTCH QRP Web site for the FY 2017 payment determination and subsequent years, with an exception regarding the way in which noncompliant LTCHs are notified of this determination.

Previously, only LTCHs found to be noncompliant with the reporting requirements set forth for a given payment determination received a notification of this finding along with instructions for requesting reconsideration in the form of a certified letter via the USPS. In an effort to communicate as quickly, efficiently, and broadly as possible with LTCHs regarding annual compliance, we proposed changes to our communications method regarding annual notification of reporting compliance in the LTCH QRP. In addition to sending a letter via regular USPS mail, beginning with the FY 2016 payment determination and for subsequent fiscal years, we proposed the QIES ASAP system as a mechanism to communicate to LTCHs regarding their compliance with the reporting requirements for the given reporting cycle.

We note that all LTCHs have been required to use the QIES ASAP system in order to report on required LTCH QRP measures since October 1, 2012. Therefore, we proposed that all Medicare-certified LTCH compliance letters be uploaded into the QIES ASAP system for each LTCH to access. Instructions to download files from QIES ASAP system may be found on the Web site at: *https://www.qtso.com/LTCH.html*. We proposed to disseminate communications regarding the availability of compliance reports in LTCHs' QIES ASAP system files through routine channels to LTCHs and vendors, including, but not limited to, issuing memos, emails, Medicare Learning Network announcements, and notices on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*.

The purpose of the compliance letter is to notify an LTCH that it has been identified as either being compliant or noncompliant with the LTCH QRP reporting requirements for the given reporting cycle. If the LTCH is determined to be noncompliant, the notification would indicate that the LTCH is scheduled to receive a 2 percentage point reduction to its upcoming annual payment update and that it may file a reconsideration request if it disagrees with this finding. LTCHs may request a reconsideration of a noncompliance determination through the CMS reconsideration request process.

We also proposed that the notification of our decision regarding received reconsideration requests will be made available through the QIES ASAP system. We did not propose to change the process or requirements for requesting reconsideration, and we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317 through 50318) for a discussion of the LTCH QRP reconsideration and appeals procedures.

We also proposed to publish a list of LTCHs that successfully meet the reporting requirements for the applicable payment determination on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*. We proposed updating the list after reconsideration requests are processed on an annual basis.

We proposed to codify the LTCH QRP reconsideration and appeal procedures at new proposed §§ 412.560(d) and (e).

We invited public comment on the proposals to change the communication mechanism to the QIES ASAP system for the dissemination of compliance notifications and reconsideration decisions, to publish a list of compliant LTCHs on the LTCH QRP Web site, and to codify these processes at new proposed §§ 412.560(d)(1) and (d)(3).

Comment: A few commenters supported the proposal to codify the reconsideration and appeals policy, although stated that CMS should clarify the exact requirements LTCHs need to meet to be in compliance with the LTCH QRP.

Response: We thank the commenters for their comments and support. While we appreciate the commenters' concern that the requirements be listed in one place, we note that the reconsideration and appeals policy will be codified and that additional technical details will be listed on our LTCH QRP Web site, on which we post guidance documents that are updated regularly. LTCHs can access the CMS LTCH QRP Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html?redirect=/LTCH-Quality-Reporting/*.

After consideration of the public comments we received, we are finalizing our proposals to change the communication mechanism to the QIES system for the dissemination of compliance notifications and reconsideration decisions, to publish a list of compliant LTCHs on the LTCH QRP Web site, to update the list after reconsideration requests are processed on an annual basis, and to codify the requirements for reconsideration and appeals, as proposed.

14. Previously Adopted and Proposed LTCH QRP Submission Exception and Extension Requirements for the FY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50883 through 50885) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50316 through 50317) for a detailed discussion of the LTCH QRP Submission Exception and Extension requirements. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24611), for the FY 2017 payment determination and subsequent years, we did not propose any changes to the LTCH QRP requirements that we adopted in these final rules. However, we proposed to codify the LTCH QRP Submission Exception and Extension Requirements at new §§ 412.560(c) and (d).

We remind readers that, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50316 through 50317), we stated that LTCHs must submit request an exception or extension by submitting a written request along with all supporting documentation to CMS via email to the LTCH mailbox at *LTCHQRPReconsiderations@cms.hhs.gov*. We further stated that exception or extension requests sent to CMS through any other channel would not be considered as a valid request for an exception or extension from the LTCH QRP's reporting requirements for any payment determination. In order to be considered, a request for an exception or extension must contain all of the requirements as outlined on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Disaster-Waiver-Requests.html*.

We invited public comments on our proposal to codify the LTCH QRP submission exception and extension requirements.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to codify the LTCH QRP submission exception and extension requirements at new §§ 412.560(c) and (d).

D. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the EHR Incentive Programs in 2016

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 (EHR) technology (CEHRT). Eligible hospitals and CAHs may qualify for these incentive payments under Medicare (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrate meaningful use of CEHRT, which includes reporting on clinical quality measures (CQMs) using CEHRT.

Sections 1886(b)(3)(B) and 1814(l) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. 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.

Under sections 1886(n)(3)(A) and 1814(l)(3)(A) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare EHR Incentive Program. The set of CQMs from which eligible hospitals and CAHs will report under the EHR Incentive Program beginning in FY 2014 is listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083).

In the EHR Incentive Program Stage 3 proposed rule [341] (80 FR 16769), to further our alignment goal among CMS quality reporting programs for eligible hospitals and CAHs and avoid redundant or duplicative reporting among hospital programs, we stated our intent to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs for 2016, 2017, and future years in the IPPS rulemaking. We further stated our belief that receiving and reviewing public comments for various CMS quality programs at one time and finalizing the requirements for these programs simultaneously would allow us to better align these programs for eligible hospitals and CAHs, allow more flexibility into the Medicare and Medicaid EHR Incentive Programs, and add overall value and consistency by providing us the opportunity to address public comments that affect multiple programs at one time.

ONC, in its 2015 Edition proposed rule (80 FR 16844), also indicated that it intends to propose certification policy for the reporting of CQMs for eligible hospitals and CAHs in or with annual IPPS rulemaking to better align with the reporting goals of other CMS programs.

2. CQM Reporting for the Medicare and Medicaid EHR Incentive Programs in 2016

a. Background

In the EHR Incentive Program Stage 2 final rule, we outlined the CQMs available for use in the EHR Incentive Programs beginning in 2014 for eligible hospitals and CAHs in Table 10 at 77 FR 54083 through 54087, as well as the form and method for submission at 77 FR 54087 through 54089. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24611 through 24613), for CQM reporting for the EHR Incentive Programs in 2016, we proposed to maintain the existing requirements established in earlier rulemaking for the reporting of CQMs, unless indicated otherwise in the proposed rule. These requirements include reporting on 16 CQMs covering at least 3 NQS domains for eligible hospitals and CAHs (77 FR 54079).

As we expand the current measures to align with the National Quality Strategy and the CMS Quality Strategy [342] and incorporate updated standards and terminologies in current CQMs, including updating the electronic specifications for these CQMs, and creating de novo CQMs, we plan to expand the set of CQMs available for reporting under the EHR Incentive Programs in CY 2017 and subsequent years. We will continue to engage stakeholders to provide input on future proposals for CQMs as well as requesting comment on future electronic specifications for new and updated CQMs.

b. CQM Reporting Period for the Medicare and Medicaid EHR Incentive Programs in CY 2016

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50319 through 50321), we began to shift CQM reporting to a calendar year basis for eligible hospitals and CAHs for the Medicare EHR Incentive Program. We established that, for eligible hospitals and CAHs that submit CQMs electronically in 2015, the reporting period is one calendar quarter

[341] Medicare and Medicaid Programs: Electronic Health Record Incentive Program—Stage 3; proposed rule (80 FR 16731 through 16804) (''EHR Incentive Program Stage 3 proposed rule'').

[342] Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html*.

from Q1, Q2, or Q3 of CY 2015 (79 FR 50321). Section 1886(n)(3)(B)(iii) of the Act requires that, in selecting measures for eligible hospitals and CAHs for the Medicare EHR Incentive Program, and establishing the form and manner for reporting measures, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under section 1886(b)(3)(B)(viii) of the Act, the Hospital IQR Program.

In the Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 Through 2017 proposed rule (80 FR 20353), beginning in 2015, we proposed to change the definition of ''EHR reporting period'' in § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period would begin and end in relation to a calendar year. In connection with that proposal, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24611 through 24612), we proposed that the reporting period for CQMs in 2016 for eligible hospitals and CAHs for the Medicare and Medicaid EHR Incentive Programs also would be based on the calendar year. We stated that we believe it is important to continue our goal of aligning the EHR Incentive Program with the Hospital IQR Program because alignment of these programs will serve to reduce hospital reporting burden and encourage the adoption and meaningful use of CEHRT by eligible hospitals and CAHs.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24581 through 24582), we proposed to require quarterly reporting and submission periods of CQMs for the 3rd and 4th CY quarters of 2016 (for the FY 2018 payment determination) of the Hospital IQR Program. We also stated that we believe it is important for us to maintain our goal of alignment between the Hospital IQR and EHR Incentive Programs. Therefore, we proposed to align the reporting period in CY 2016 for eligible hospitals and CAHs that report CQMs electronically for the Medicare EHR Incentive Program with that of the Hospital IQR Program and require quarterly reporting and submission periods for CQMs in the 3rd and 4th CY quarters. We refer readers to section VIII.A.8.c. of the preamble of this final rule for further discussion of the proposals and our finalized policies for the Hospital IQR Program.

In addition, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24587 through 24588), we proposed to change the Hospital IQR Program's submission period for CQMs from annual to quarterly submission, and proposed to change the submission deadline from November 30, 2015 to ending 2 calendar months after the close of the reporting CY quarter (for CY 2016/FY 2018 payment determination, the proposed deadlines are November 30, 2016 for Q3 and February 28, 2017 for Q4). We refer readers to the Hospital IQR Program discussion in section VIII.A.10.d.(3) of the preamble of this final rule for more information about these proposals. Therefore, to coincide with the submission period in the Hospital IQR Program, we also proposed to align the Medicare EHR Incentive Program submission period for CY 2016 with the submission period proposed for the Hospital IQR Program.

We proposed the following CQM reporting periods and submission deadlines for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program in CY 2016:

- Eligible hospitals and CAHs Reporting CQMs by Attestation

++ For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2016, any continuous 90-day reporting period within CY 2016; or one full calendar year reporting period for CY 2016. Attestation by February 28, 2017.

++ For eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2016, one full calendar year reporting period for CY 2016. Attestation by February 28, 2017.

- Eligible hospitals and CAHs Reporting CQMs Electronically —Two full quarters of data (Q3 and Q4 of CY 2016) submitted via electronic reporting within 2 months after the close of each quarter (Q3 by November 30, 2016; Q4 by February 28, 2017).

We also proposed that the CQM reporting period for eligible hospitals and CAHs participating in the Medicaid EHR Incentive Program would be any continuous 90-day reporting period within CY 2016 for eligible hospitals and CAHs demonstrating meaningful use for the first time; and one full calendar year reporting period of CY 2016 for eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2016. Providers should refer to their State Medicaid program for requirements on submission methods and deadlines.

We note that, beginning in CY 2017 and in subsequent years, we proposed in the EHR Incentive Program Stage 3 proposed rule (80 FR 16739 through 16740) to require a reporting period of one full calendar year for CQM reporting for all providers participating in the EHR Incentive Programs, with a limited exception for Medicaid providers demonstrating meaningful use for the first time.

We invited public comment on these proposals.

Comment: A few commenters supported the proposal to maintain the existing CQM requirement to report on 16 CQMs covering at least 3 NQS domains. Many commenters expressed concern that hospitals are not prepared to submit electronic CQMs. Several commenters noted that electronic CQM reporting is difficult for hospitals due to the complexities involved in implementing EHRs. As a result of these concerns, many commenters requested an extension in the roll-out of this requirement, if finalized, in order to allow hospitals time to prepare to meet reporting requirements and to allow more time to overcome the challenges associated with electronic reporting. Many of these commenters supported CMS' goal to move towards electronic reporting, but specifically requested that CMS delay a requirement for hospitals to report CQMs electronically until CY 2018, in order to align with the EHR Incentive Program proposals in the Stage 3 proposed rule. Some commenters recommended that CMS require electronic CQM reporting no sooner than CY 2017.

Response: We appreciate the commenters' support of our proposal to maintain the existing CQM requirement to report on 16 CQMs covering at least 3 NQS domains. In addition, we recognize the challenges associated with electronic reporting and appreciate the comments we received. In this final rule, we are modifying the proposed requirement for electronically submitted CQMs for the reporting period in CY 2016. In an effort to align with the Hospital IQR Program and reduce the burden for hospitals, rather than reporting on a minimum of 16 CQMs covering at least 3 NQS domains as proposed, we are requiring hospitals that submit CQMs electronically for the Medicare EHR Incentive Program to report on a minimum of 4 CQMs for the reporting period in 2016 with no NQS domain distribution requirement. This reduction from a minimum of 16 CQMs to a minimum of 4 CQMs and the elimination of the NQS domain distribution requirement only apply for hospitals that choose to report CQMs through electronic submission. Hospitals that choose to report CQMs by attestation for the reporting period in 2016 are required to report on a minimum of 16 CQMs covering at least 3 NQS domains. Further, we are modifying our proposed requirement for hospitals reporting CQMs through electronic submission to report two full quarters of data (Q3 and Q4 of CY 2016) within 2 months after the close of each

quarter. Instead, we are requiring only one full quarter of data (either Q3 or Q4 of CY 2016), with a submission deadline of February 28, 2017, to allow more time for hospitals to implement their EHR programs and overcome the challenges associated with electronic reporting of CQMs. We believe electronic reporting of CQMs is an important next step in the meaningful use of certified EHR technology, and anticipate that this lower reporting threshold and extended submission deadline for electronically submitted CQMs will reduce burden and encourage eligible hospitals and CAHs to report electronically for 2016. We also anticipate increasing this number in future rules to retain the 16 measure requirement. We believe that a full year should be adequate time for hospitals to address their mapping issues and that it is important to continue to make progress towards electronic reporting.

We refer readers to the Hospital IQR Program discussion in section VIII.A.8.c. of the preamble of this final rule for further discussion of these and other related comments and our responses.

Comment: Several commenters supported the proposal to base the reporting period on the calendar year. Other commenters supported the proposal to require quarterly reporting and submission periods for electronically submitted CQMs as well as to change the submission period for CQMs from annual to quarterly submission. The commenters generally supported the alignment efforts between the EHR Incentive Program and the Hospital IQR Program. One commenter suggested that the submission timeline be extended to one full quarter instead of the proposed 2 calendar months.

Response: We refer readers to the Hospital IQR Program discussion in section VIII.A.10.d.(3) of the preamble of this final rule for further discussion of these and other related comments and our responses.

After consideration of the public comments we received, and with further consideration of the discussion in sections VIII.A.8.c. and VIII.A.10.d.(3) of the preamble of this final rule, we are aligning our reporting periods and requirements for electronically submitted CQMs for the Medicare EHR Incentive Program with the reporting periods and requirements for electronically submitted CQMs for the Hospital IQR Program. Specifically, we are not finalizing our proposals to require 16 CQMs across three NQS domains reported quarterly for Q3 and Q4 of 2016. Instead, for hospitals that choose to report CQMs electronically for the Medicare EHR Incentive Program for the reporting period in CY 2016, we are requiring a minimum of 4 electronically submitted CQMs in either Q3 or Q4 of CY 2016, with a submission deadline of February 28, 2017. We note that this final policy does not change the reporting periods or requirements for the meaningful use objectives and associated measures under 42 CFR part 495 or apply for CQMs that are reported by attestation via the Registration and Attestation System. We further note that providers should refer to their State Medicaid program for requirements on submission methods and deadlines for the Medicaid EHR Incentive Program.

c. CQM Reporting Form and Method for the Medicare EHR Incentive Program in 2016

In the EHR Incentive Program Stage 2 final rule (77 FR 54087 through 54089), we finalized the reporting methods for eligible hospitals and CAHs for the Medicare EHR Incentive Program, which included reporting electronically or by attestation. We finalized that eligible hospitals and CAHs that are beyond their first year of meaningful use will be required to electronically submit the selected 16 CQMs. Subsequent to the Stage 2 final rule, we determined that electronic submission of aggregate-level data using QRDA–III would not be feasible in 2014 and 2015, and thus, eligible hospitals and CAHs would have the option to continue to report aggregate CQM results through attestation for the reporting periods in 2014 and 2015 (78 FR 50904 through 50905; 79 FR 50321 through 50322).

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24612 through 24613), we proposed to continue our existing policy that eligible hospitals and CAHs in any year of participation in the Medicare EHR Incentive Program in 2016 may report CQMs by attestation or electronically using the options previously outlined for electronic reporting either for single program participation in the Medicare EHR Incentive Program, or for participation in multiple programs if the requirements of the aligned quality program are met. The options for CQM submission for eligible hospitals and CAHs in the Medicare EHR Incentive Program are as follows:

- Eligible hospital and CAH options for Medicare EHR Incentive Program participation *(single program participation)*

++ Option 1: Attest to CQMs through the EHR Registration & Attestation System.

++ Option 2: Electronically report CQMs through QualityNet Portal.

- Eligible hospital and CAH options for electronic reporting for multiple programs *(for example: EHR Incentive Program plus Hospital IQR Program participation)*—Electronically report through QualityNet Portal.

For the Medicaid EHR Incentive Program, States will 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.

We proposed to continue our policy that electronic submission of CQMs will require the use of the most recent release of the CQM version for each CQM to which the EHR is certified. For electronic reporting in 2016, this means eligible hospitals and CAHs would be required to use the Spring 2015 release of the CQMs available at the CMS eCQM Library (*http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*). We noted that an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the CQMs. (For further information on CQM reporting, we refer readers to the EHR Incentive Program Web site where guides and tip sheets are available for each reporting option (*www.CMS.gov/ehrincentiveprograms*).) However, we stated that we encourage EHR developers to test any updates, including any changes to the CQMs and changes to the CMS reporting requirements based on the CMS QRDA implementation guide, on an annual basis.

The form and method of electronic submission are further explained in subregulatory guidance and the certification process. For example, the following documents are updated annually to reflect the most recent CQM electronic specifications: The CMS QRDA Implementation Guide; program specific performance calculation guidance; and CQM electronic specifications and guidance documents. These documents are located on the CMS eCQM Library (*http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*).

We invited public comments on this proposal.

Comment: Several commenters supported the proposal to allow eligible hospitals and CAHs to report CQMs by

attestation or electronically. A few commenters stated that they would prefer to attest to their CQMs than to submit them electronically.

Response: We appreciate the commenters' support of our proposal.

Comment: Some commenters noted that the Hospital IQR Program is not required for CAHs, and requested clarification on how the alignment between the Hospital IQR Program and the EHR Incentive Program for electronically submitted CQMs and the method of reporting would impact CAHs seeking to electronically submit their CQM data.

Response: We agree that the Hospital IQR Program is not required for CAHs. Only subsection (d) hospitals are subject to the requirements and payment reductions of the Hospital IQR Program. For the EHR Incentive Program, CAHs may continue to report their CQM data by attestation in CY 2016. However, we encourage CAHs to submit their CQMs electronically through the QualityNet portal. We believe electronic submission of CQMs is an important next step in the meaningful use of certified EHR technology, and encourage CAHs to begin submitting CQMs electronically in 2016. We further note that, in the Stage 3 proposed rule (80 FR 16770), CMS has proposed to require electronic submission of CQMs starting in 2018 and thus encourage CAHs to begin electronically reporting CQMs as soon as feasible.

Comment: Several commenters expressed concerns regarding the timing of the annual update cycle for CQMs and stated that EHR vendors need more time to update their EHRs. Some commenters suggested that updates be minimal, or that the new specifications for CQMs be released well in advance of their implementation.

Response: We appreciate the commenters' concerns, and note that the CQM electronic specifications are posted at least 6 months prior to the reporting period. We believe it is important to reflect the most recent clinical guidance in CQMs, and therefore seek to find an appropriate balance between the timing of the posting of CQM electronic specifications and the reporting period for those CQMs.

Comment: Several commenters again requested clarification as to whether vendors would be required to recertify their EHRs when CQMs are updated. A few commenters suggested that recertification be required with each update to the CQMs.

Response: We appreciate this feedback and note that, under our policy stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50323), an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the CQMs. However, we encourage EHR developers to test any updates, including any changes to the CQMs and changes to the CMS reporting requirements based on the CMS QRDA implementation guide, on an annual basis.

After consideration of the public comments we received, we are finalizing our proposals to allow eligible hospitals and CAHs in any year of participation in the Medicare EHR Incentive Program in 2016 to report CQMs by attestation or electronically, and to continue our policy that electronic submission of CQMs will require the use of the most recent release of the CQM version. We note that an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the CQMs.

Several commenters sought clarification regarding the requirement to submit QRDA–I data, and asking whether the QRDA–III option would be available to eligible hospitals and CAHs for reporting to the EHR Incentive Program and the Hospital IQR Programs. We note that, in the EHR Incentive Program Stage 3 proposed rule (80 FR 16771), we proposed to remove the QRDA–III option for eligible hospitals and CAHs. Therefore, we refer readers to that proposed rule for further discussion of this proposal. Due to the timing of the expected publication of the Stage 3 final rule and the questions raised concerning this topic in the public comments on the FY 2016 IPPS/LTCH PPS proposed rule, we are addressing our proposal to remove the QRDA–III option in this FY 2016 IPPS/LTCH PPS final rule instead of in the upcoming Stage 3 final rule. We note the public comment period for the Stage 3 proposed rule ended on May 29, 2015 (80 FR 16732). Below is a summary of the public comments we received in response to our proposal in the Stage 3 proposed rule to remove the QRDA–III option, as well as comments received on this topic in response to the FY 2016 IPPS/LTCH PPS proposed rule.

Comment: Many commenters stated concerns over patient privacy using the QRDA–I submission method and stated that no personally identifiable information should be collected for quality reporting purposes.

Response: While we appreciate the commenters' concerns, we believe patient privacy is protected through the security precautions put in place to collect QRDA–I data. With the QualityNet Secure Portal's release in July 2014, CMS complied with OMB Memorandum 04–04, which requires all Federal systems that collect Protected Health Information (PHI) and are accessed electronically to implement identity management processes, which include both identity proofing and user authentication. Identity proofing and user authentication also are requirements of the Federal Information Security Management Act (FISMA) and National Institute of Standards and Technology (NIST), as well as the HIPAA Security Rule. In addition, the system is required to have multi-factor authentication which provides unambiguous identification of users by means of the combination of two different components. The use of two-factor authentication (a type of multifactor authentication) to prove one's identity is based on the premise that an unauthorized actor is unlikely to be able to supply both factors required for access. If, in an authentication attempt, at least one of the components is missing or supplied incorrectly, the user's identity is not established with sufficient certainty and access to the asset (for example, data) being protected by two-factor authentication then remains blocked.

Comment: Several commenters were concerned about the complexity of coding and build efforts of the QRDA–I functionality. The commenters stated that the development and implementation effort of the QRDA–I was more complex than QRDA–III. Some commenters stated that EHR vendors were not prepared to produce QRDA–I files. Some commenters requested that CMS maintain the QRDA–III format for hospital quality reporting. A few commenters outlined the benefits of the QRDA–III format, and stated that it is easier to implement than QRDA–I, less time-consuming to submit, provides transparency, and is a more mature standard.

Response: We understand and appreciate that some commenters prefer the QRDA–III over the QRDA–I. However, the QRDA–I provides patient-centric data and measure calculations independent of the EHR Incentive Program, which allows CMS to verify the data for future use in the Hospital VBP Program.

After consideration of the public comments we received, and in consideration of the limitations outlined above, we are finalizing our proposal to remove the QRDA–III as an option for reporting under the Medicare EHR Incentive Program. For 2016 and future

years, we are requiring QRDA–I for CQM electronic submissions for the Medicare EHR Incentive Program. We note that QRDA–I data are essential for data verification for the Hospital VBP Program, and are protected by CMS privacy standards. We also note that States would continue to have the option, subject to our prior approval, to allow or require QRDA–III for CQM reporting.

3. ''CQMs—Report'' Certification Criterion in ONC's 2015 Edition Proposed Rule

In the 2015 Edition proposed rule (80 FR 16814), ONC proposed a 2015 Edition certification criterion for ''CQMs—report'' [343] at proposed new 45 CFR 170.315(c)(3) as part of the proposed 2015 Edition of certification criteria that would require a certified Health IT Module to enable a user to electronically create a data file for transmission of clinical quality measurement data using the ''base'' HL7 (that is, industry-wide, non-program-specific) QRDA Category I and Category III standards, at a minimum. ONC also proposed to allow optional certification for EHRs according to the CMS ''form and manner'' requirements defined in CMS' QRDA Implementation Guide [344] as part of this proposed criterion. We reiterate that this proposed certification criterion would apply to EPs, eligible hospitals, and CAHs.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24613 through 24614), for the requirements for the 2015 Edition certification criteria, ONC proposed the following at proposed new § 170.315(c)(3) for clinical quality measurement to state that technology certified to the 2015 Edition must enable a user to electronically create a data file for transmission of clinical quality measurement data which is:

- At a minimum, in accordance with the standards specified in § 170.205(h) and § 170.205(k); and
- Optionally, can be electronically accepted by CMS.

As detailed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24613 through 24614), ONC solicited public comment on the versions of the Quality Reporting Document Architecture—Category I standard that should be adopted under § 170.205(h) and the versions of the Quality Reporting Document Architecture—Category III standard that should be adopted under § 170.205(k) for individual patient level and aggregate level reports, respectively. In order to give full consideration to the public comments received on the versions of the standards that should be adopted under § 170.205(h) and (k), we are not finalizing the ''CQMs-report'' certification criterion in this FY 2016 IPPS/LTCH PPS final rule. We anticipate finalizing both the certification criterion and the versions of the standards that should be adopted for this criterion in a subsequent final rule later this year. We also intend to address public comments received on both the proposed ''CQMs-report'' certification criterion and the versions of the standards that should be adopted for this criterion in that same rule.

4. CQM Development and Certification Cycle

We stated in the EHR Incentive Program Stage 2 final rule (77 FR 54055) that we do not intend to use notice-and-comment rulemaking as the means to update or modify CQM specifications. Given the necessity to update CQM specifications after they have been published to ensure their continued clinical relevance, accuracy, and validity, we publish annual updates to the electronic specifications for EHR submission. Although we require eligible hospitals and CAHs to submit the most updated versions of CQMs when reporting electronically, CEHRT is not required to be recertified on annual basis. CMS and ONC understand that standards for electronically representing CQMs continue to evolve, and believe there may be value in retesting certified Health IT Modules (including CEHRT) periodically to ensure that CQMs are being accurately calculated and represented, and that they can be reported to CMS in the ''form and manner'' required for the Hospital IQR Program and EHR Incentive Program. As mentioned previously, CMS and ONC encourage health IT developers to retest their certified technology annually, and solicited public comments on the appropriate frequency for requiring retesting and recertification to the most updated versions of CQMs and most recent ''form and manner'' reporting requirements.

However, given the continuing evolution of technology and clinical standards, as well as the need for a predictable cycle from measure development to provider data submission, CMS intends to publish a request for information (RFI) on the establishment of an ongoing cycle for the introduction and certification of new measures, the testing of updated measures, and the testing and certification of submission capabilities. We encourage readers to submit their insights and recommendations for our consideration upon publication of that RFI.

Comment: Several commenters noted the upcoming RFI and stated their intention to comment further when that RFI becomes available.

Response: We look forward to the comments submitted via the upcoming RFI, and note that we will consider all comments before proposing a change to our policies.

Comment: Some commenters expressed concern with the timing of the annual update, stating that the publication date of the IPPS final rule in late summer, with an implementation date of the updates of January 1, does not allow adequate time to implement the CQM changes in the annual update. Some commenters stated that there should be a minimum of 18 months between the time of the annual update and when the updates need to be implemented. Some commenters suggested that CQMs changes in the annual update be limited only to nonsubstantive changes and those changes that do not require a change to provider work flows.

Response: We appreciate these comments and feedback. CQMs are updated routinely to account for changes, including, but not limited to, changes in billing and diagnosis codes and changes in medical practices. In order for CQMs to remain current and clinically valid, the specifications must be updated on a regular basis. We note that CQM electronic specifications are posted at least 6 months prior to the start of the reporting period, and well in advance of the submission window. While we understand that this does not allow the suggested 18 months for vendors to update their EHR products, we believe this timeframe allows an adequate amount of time to make those updates while ensuring that the CQMs are still current and clinically valid once implemented.

Comment: Several commenters suggested that use of the most recent CQM electronic specifications not be required unless EHR vendors also are required to update and recertify their EHR products.

Response: We appreciate the commenters' feedback. However, we note that it is not technically feasible for CMS to accept multiple versions of the

[343] As noted in the 2015 Edition proposed rule, ONC proposed to title proposed new § 170.315(c)(3) ''CQMs—report'' to better align with the use of the term ''report'' throughout the 2015 Edition. Also, ONC proposed to discontinue to reference ''electronic'' in the title of certification criteria as it is assumes that all functions performed by certified health IT are done electronically. See 80 FR 16844.

[344] The CMS QRDA Implementation Guide can be accessed at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*.

CQM specifications. In addition, we note that the most recent version of the CQM electronic specifications is required to ensure that the most current and clinically valid version of the CQM is being implemented and used. We also have received feedback from stakeholders regarding the difficulty and expense of having to test and recertify CEHRT products to the most recent version of the electronic specifications for the CQMs. While we still believe that vendors should test and certify their products to the most recent version of the electronic specifications for the CQMs when feasible, we understand the burdens associated with this requirement and therefore do not require that CEHRT products be recertified to the most recent version of the electronic specifications for the CQMs with the annual update.

IX. 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 2015 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2016 are addressed in Appendix B to this final 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 Web site at: *http://www.medpac.gov*.

X. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We listed the data files and the cost for each file, if applicable, in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24615 through 24616).

Commenters interested in discussing any data used in constructing this final rule should contact Chioma Obi at (410) 786–6050.

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 the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24616 through 24621), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Add-On Payments for New Services and Technologies

Sections II.I.1. of the preambles of the proposed rule (80 FR 24418 through 24463) and this final rule discuss add-on payments for new services and technologies. Specifically, this section states that applicants for add-on payments for new medical services or technologies for FY 2017 must submit a formal request. A formal request includes 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. In addition, the request must contain a significant sample of the data to demonstrate that the medical service or technology meets the high-cost threshold.

We believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. For FYs 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, and 2016, we received 1, 4, 5, 3, 3, 5, 5, 7, and 9 applications, respectively. We note that two of the nine applications received for FY 2016 were withdrawn after publication of the proposed rule, as indicated in section III.I. of the preamble of this final rule.

We did not receive any public comments regarding this information collection.

3. ICRs for the Occupational Mix Adjustment to the FY 2016 Wage Index (Hospital Wage Index Occupational Mix Survey)

Sections III.E. and F. of the preambles of the proposed rule (80 FR 24465 through 24467) and this final rule discuss the occupational mix adjustment to the proposed and final FY 2016 wage index, respectively. While the preambles of these rules do not contain any new ICRs, we note that there is an OMB approved information collection request associated with the hospital wage index.

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data at least once 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. We collect the data via the occupational mix survey.

The burden associated with this information collection requirement is the time and effort required to collect and submit the data in the Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned burden is subject to the PRA; it is currently approved under OMB control number 0938–0907.

We did not receive any public comments regarding this information collection.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Sections III.J.2. of the preambles of the proposed rule (80 FR 24470 through 24471) and this final rule discuss proposed and finalized changes to the wage index based on hospital reclassifications, respectively. As stated in those sections, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage

index and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. The burden associated with this requirement is subject to the PRA. It is currently approved under OMB control number 0938–0573.

We did not receive any public comments regarding this information collection.

5. Simplified Cost Allocation Methodology for Hospitals

In sections IV.H. of the preamble of the proposed rule (80 FR 24514 through 24515), we discussed our proposal to amend the regulations at 42 CFR 412.302(d)(4) to limit a hospital's ability to elect the simplified cost allocation methodology under the terms and conditions provided in the instructions for CMS Form 2552 to cost reporting periods beginning before October 1, 2015. After consideration of the public comments we received, we are not finalizing our proposal to limit the election of the simplified cost allocation methodology in this final rule. Instead, we are retaining the simplified cost allocation methodology with some modifications to afford hospitals using the simplified cost allocation methodology flexibility to obtain approval from their MACs to use dollar value as an alternative statistical basis to square footage for capital-related moveable equipment. Based on FY 2013 HCRIS data, less than 100 hospitals have elected to use the simplified cost allocation methodology.

Although we are not finalizing our proposal to eliminate the simplified cost allocation methodology for hospitals, but instead are affording hospitals greater flexibility to obtain approval from their MAC to use dollar value as an alternative statistical basis to square footage for capital related moveable equipment, we believe the currently approved burden estimates for the Hospital and Health Care Complex Cost Report (OMB control number 0938–0050) are still applicable to hospitals completing the Hospital and Health Care Complex Cost Report. The time required to address this revision will be subsumed in the total burden estimate for an entity to comply with all of the requirements in the cost report.

We did not receive any public comments regarding this information collection.

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

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. This program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a ''starter set'' of 10 quality measures. 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 previously approved under OMB control number 0938–1022. We no longer use OMB control number 0938–0918.

We added additional quality measures to the Hospital IQR Program and submitted the information collection request to OMB for approval. This expansion of the Hospital IQR Program measures was part of our implementation of section 5001(a) of the DRA. Section 1886(b)(3)(B)(viii)(III) of the Act, added by section 5001(a) of the DRA, requires that the Secretary expand the ''starter set'' of 10 quality measures that were established by the Secretary as of November 1, 2003, to include measures that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings. The burden associated with these reporting requirements is currently approved under OMB control number 0938–1022.

In section VIII.A.6. of the preamble of this final rule, we are finalizing modified versions of our proposed refinements to expand the measure cohorts for: (1) The Hospital 30-Day All-Cause, Risk-Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization measure (NQF #0468); and (2) the Hospital 30-Day All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506). Expanding the measure cohorts to include a broader population of patients adds a large number of patients, as well as additional hospitals, to these measures. However, this expansion will not affect the hospitals' burden because these measures are claims-based and, therefore, require no additional effort on hospitals' part to submit the required data.

In section VIII.A.7. of the preamble of this final rule, we are finalizing seven of the eight additional proposed measures to the Hospital IQR Program measure set. The seven new measures are: (1) Hospital Survey on Patient Safety Culture (structural); (2) Kidney/UTI Clinical Episode-Based Payment (claims-based); * (3) Cellulitis Clinical Episode-Based Payment (claims-based); * (4) Gastrointestinal Hemorrhage Clinical Episode-Based Payment (claims-based); * (5) Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based); (6) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (claims-based); and (7) Excess Days in Acute Care after Hospitalization for Heart Failure (claims-based). We are not finalizing our proposal to add the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment (claims-based) measure. Four of these seven measures are being finalized for the FY 2018 payment determination and subsequent years as proposed; however, the other three measures, addressing clinical episode-based payments and denoted with an (*), are being finalized for the FY 2019 payment determination and subsequent years—a modification to what was proposed.

One new measure is structural; the remaining six new measures are claims-based. The burden associated with collecting information on the structural measure we are finalizing, Hospital Survey on Patient Safety Culture, is expected to be minimal, as it involves filling out a one-time form to report on this measure for a given performance period; therefore, its addition will not result in a significant burden increase. In total, we estimate a burden of 15 minutes per hospital to complete other forms such as the ECE and Measure Exception form, and to report structural measures. The estimate of 15 minutes includes all previously finalized and newly required structural measures. Because the remaining measures we are finalizing are claims-based measures and can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional information collection will be required from the hospitals for the six newly finalized claims-based measures.

We also are finalizing our proposals to remove nine measures. We believe that there will be a reduction in collection of information burden for hospitals due to our removal of seven of these nine measures, which are chart-abstracted: (1) STK–01 Venous Thromboembolism

Prophylaxis (NQF #0434); (2) STK–06: Discharged on Statin Medication ** (NQF #0439); (3) STK–08: Stroke Education ** (NQF endorsement removed); (4) VTE–1: Venous Thromboembolism Prophylaxis ** (NQF #0371); (5) VTE–2: Intensive Care Unit Venous Thromboembolism Prophylaxis ** (NQF #0372); (6) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy ** (NQF #0373); and (7) AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival ** (NQF #0164). (A double asterisk (**) indicates that we finalized our proposal to retain the measure as an electronic clinical quality measure for the FY 2018 payment determination and subsequent years in section VIII.A.8. of the preamble of this final rule.) Due to the burden associated with the collection of chart-abstracted data, we estimate that the removal of AMI–7a will result in a burden reduction of approximately 219,000 hours across all hospitals. In addition, we estimate that the removal of 6 VTE and STK chart-abstracted measures will result in an information collection burden reduction of approximately 522,000 hours across all hospitals.

The remaining two of the nine measures finalized for removal have been previously suspended from the Hospital IQR Program. Therefore, their removal will not affect information collection burden to hospitals. These measures are: IMM–1 Pneumococcal Immunization (NQF #1653); and SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300). The suspension of IMM–1 is currently reflected under OMB control number 0938–1022. The suspension of SCIP-Inf-4, which was formalized on January 9, 2015,[345] will be reflected in the PRA package being submitted this year under OMB control number 0938–1022. In total, we estimate that the removal of 9 measures will result in a total information collection burden reduction of approximately 741,000 hours for the FY 2018 payment determination across all hospitals.

For the FY 2018 payment determination, we also are finalizing a modification of our proposals regarding electronic clinical quality measures. Instead of requiring hospitals to report 16 electronic clinical quality measures, we are requiring a minimum of 4 electronic clinical quality measures. Under this modified policy, no NQS domain distribution will be required. In addition, for the FY 2018 payment determination, instead of requiring two quarters of data, we are requiring that hospitals submit only one quarter of eCQM data (either Q3 or Q4) of CY 2016, by February 28, 2017. We also anticipate increasing the number of required electronic clinical quality measures in future rules to propose a 16 measure requirement. We believe that a full year should be enough time for hospitals to address their mapping issues and that it is important to continue to make progress towards electronic reporting.

Lastly, in response to comments suggesting that QRDA I be required and other comments requesting clarification on our QRDA requirement, we are finalizing a modification of our proposal modifying our electronic clinical quality measure reporting requirements to include the a policy requirement that hospitals must report via QRDA I. We believe the delayed reporting period and submission deadlines finalized will provide hospitals with adequate time to prepare to report using QRDA I.

We believe that the total information collection burden associated with the electronic clinical quality measure reporting proposal can be drawn from the burden outlined for hospitals in the EHR Incentive Program Stage 2 final rule (77 FR 54126 through 54133). In that final rule, the burden estimate for a hospital to attest and report 16 electronic clinical quality measures is 2 hours and 40 minutes per quarter (77 FR 54132). In total, we expect the burden associated with our finalized policy to require hospitals to report 4 electronic clinical quality measures for one quarter of data to be 40 minutes per hospital, and 2,200 hours total across the approximately 3,300 hospitals participating in the Hospital IQR Program. We do not anticipate any observed change in burden as it relates to the reporting via QRDA I.

We estimate that reporting these electronic clinical quality measures can be accomplished by staff with a mean hourly wage of $16.42 per hour.[346] Under OMB Circular A–76, in calculating direct labor, agencies should not only include salaries and wages, but also ''other entitlements'' such as fringe benefits.[347] This Circular provides that the civilian position full fringe benefit cost factor is 36.25 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $22.37 ($16.42 base salary + $5.95 fringe) and a total cost of $49,214 (2,200 hours × $22.37 per hour) across approximately 3,300 hospitals participating in the Hospital IQR Program to report 4 electronic clinical quality measures for either Q3 or Q4 of CY 2016.

We are finalizing our proposal to change the requirements for population and sampling such that hospitals will be required to submit population and sample size data only for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program. We believe this finalized proposal will result in a minimal decrease in information collection burden as hospitals will not have to report population and sample size if they electronically report any of the measures that can be reported either as an electronic clinical quality measure or via chart-abstraction.

We also are finalizing our proposal to modify the existing processes for validation of chart-abstracted Hospital IQR Program data to remove one stratum. We anticipate that if there is any affect, it will be that this modification will minimally reduce hospital burden regarding the collection of information. For validation of chart-abstracted data for the FY 2018 payment determination and subsequent years, we require hospitals to provide 72 charts per hospital per year (with an average page length of 1,500), including 40 charts for HAI validation and 32 charts for clinical process of care validation, for a total of 108,000 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page (79 FR 50346) for a total per hospital cost of $12,960. For hospitals providing charts digitally via a re-writable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we will reimburse hospitals at a rate of 40 cents per disc. We do not believe any additional burden is associated with data submitting this information via Web portal or PDF.

Under OMB number 0938–1022, we estimated that the total burden associated with collection of information and with other activities such as sampling and validation for the FY 2017 payment determination was 1,781 hours per hospital and 5.9 million hours across approximately 3,300 hospitals participating in the Hospital IQR Program. Using data on chart-abstracted measures from the 3rd quarter in 2013 through the 2nd quarter in 2014, we have revised our burden estimate to include updates to the number of records reported per measure set, as well as the time associated with

[345] QualityNet. Available at: *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890406532&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D2015-02-IP.pdf&blobcol=urldata&blobtable=MungoBlobs.*

[346] *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html.*

[347] *http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.*

data collection. Considering the proposals finalized in this final rule, as well as our updated estimates for the number of records reported and the time associated with data reporting activities, we estimate a total burden of 2,289 hours per hospital and 7.6 million hours across approximately 3,300 hospitals participating in the Hospital IQR Program for the FY 2018 payment determination. Of the 7.6 million hours estimated for the total burden, 7.4 million hours are associated with collection of information activities and 0.2 million hours are associated with other activities such as population and sampling, and validation. This burden estimate includes the full measure set finalized for the Hospital IQR Program FY 2018 payment determination and accounts for burden changes associated with all newly finalized measures as well as measures finalized for removal, as discussed above in this section.

This burden estimate accounts for other activities such as population and sampling, reviewing reports for claims-based measure sets, HAI validation templates, as well as all other forms and structural measures. The estimate excludes the burden associated with the NHSN and HCAHPS measures, both of which are submitted under separate information collection requests and are approved under OMB control numbers 0920–0666 and 0938–0981, respectively. The burden estimates in this final rule are the estimates for which we are requesting OMB approval.

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in sections VIII.B. of the preambles of the proposed rule (80 FR 24590) and this final 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.

In section VIII.B.3. of the preamble of this final rule, we are finalizing our policy that PCHs must submit data on three additional measures beginning with the FY 2018 program: (1) CDC NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) CDC NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and (3) CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel (HCP) Measure (NQF #0431). In conjunction with finalizing our policy in section VIII.B.2. of the preamble of this final rule to remove the six SCIP measures from the PCHQR Program beginning with fourth quarter (Q4) 2015 discharges and for subsequent years, the PCHQR measure set will consist of 16 measures beginning with the FY 2018 program.

With respect to finalizing our policy to add three measures beginning with the FY 2018 program, this estimate excludes the burden associated with two of these measures (the CDC NHSN MRSA measure and the CDC NHSN CDI measure), both of which are submitted under separate information collection requests and are approved under a separate OMB control number (0920–0666).[348] Using the same methodology as the FY 2015 IPPS/LTCH PPS final rule,[349] for the third finalized new measure (CDC NHSN HCP measure), we estimate that it will take 10 minutes annually per PCH, or an additional 1.83 hours for all PCHs annually to report the measure.[350]

Our finalized policy to remove six SCIP measures will reduce the burden experienced by PCHs. We estimate a reduction in hourly burden of 6,468 [351] hours per year beginning with Q4 2015 and for subsequent program years across the 11 PCHs.

In summary, as a result of our finalized policies, we estimate a reduction of 6,466.17 [352] hours of burden per year associated with the reporting for all 11 PCHs beginning with the FY 2018 program. Coupled with our estimated salary costs,[353] we estimate that these changes will result in a reduction in annual labor costs of $426,767.22 beginning with the FY 2018 PCHQR Program.

Comment: One commenter supported CMS' efforts to reduce reporting burden. However, the commenter stated that CMS had not considered the total burden associated with data collection for the hospital-wide surveillance efforts, the development of technical infrastructure, and resources to ensure consistent application of measures specifications.

Response: We appreciate the commenter's support. Because we are leveraging the CDC NHSN system in data collection, we confirmed with the CDC that all burden associated with the three measures (CDC NHSN MRSA, CDC NHSN CDI, and CDC NHSN HCP measures) that we are finalizing, including the burden associated with the activities mentioned by the commenter, has been accounted for under the OMB control number 0920–0666.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In sections IV.F. of the preamble of the proposed rule (80 FR 24498 through 24509) and this final rule, we discuss requirements for the Hospital VBP Program. Specifically, in this final rule, we are finalizing our proposal to adopt one new measure beginning with the FY 2018 program year, the 3-Item Care Transition Measure (CTM–3) (NQF #0228). We also are finalizing our proposal to adopt one new measure beginning with the FY 2021 program year, the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization Measure (NQF #1893) (MORT–30–COPD).

As required under section 1886(o)(2)(A) of the Act, both of these additional measures are required for the Hospital IQR Program. Therefore, their inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

9. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

As discussed in sections VIII.C.5.a and VIII.C.5.b. of the preamble of this final rule, we are retaining the following 12 previously finalized quality measures for use in the LTCH QRP:

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[348] OMB Control Number History. Available at: *http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0920-0666*.

[349] FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50444).

[350] Ibid.

[351] [(49 cases per measure × 4 quarters) + 0.5 (abstraction/training time)] × 11 PCHs = 6,468 hours per year.

[352] 6,468 hours − 1.83 hours = 6,466.17 hours.

[353] 6,466.17 hours * $66/hour. [We are now estimating an hourly salary of $33 (*http://swz.salary.com/salarywizard/Staff-Nurse-RN-Hourly-Salary-Details.aspx*). After accounting for employee benefits and overhead, this results in a total cost of $66 per labor hour].

LTCH QRP QUALITY MEASURES PREVIOUSLY ADOPTED FOR THE FY 2015 AND FY 2016 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS

NQF ID	Measure title	Payment determination	Final rule(s) in which measure was finalized
NQF #0138	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	FY 2015 payment determination and subsequent years.	FY 2012 IPPS/LTCH PPS final rule; updated in FY 2013 IPPS/LTCH PPS final rule.
NQF #0139	National Healthcare Safety Network (NHSN) Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure.	FY 2015 payment determination and subsequent years.	FY 2012 IPPS/LTCH PPS final rule; updated in FY 2013 IPPS/LTCH PPS final rule.
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay).	FY 2015 payment determination and subsequent years*.	FY 2012 IPPS/LTCH PPS final rule; updated in FY 2014 IPPS/LTCH PPS final rule.
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).	FY 2016 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.
NQF #0431	Influenza Vaccination Coverage Among Healthcare Personnel.	FY 2016 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.

*Adopted in this FY 2016 IPPS/LTCH PPS final rule for the FY 2018 payment determination and subsequent years

LTCH QRP QUALITY MEASURES PREVIOUSLY ADOPTED FOR THE FY 2017 AND FY 2018 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS

NQF ID	Measure title	Payment determination	Final rule(s) in which measure was finalized
NQF #1716	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	FY 2017 and Subsequent Years.	FY 2014 IPPS/LTCH PPS final rule.
NQF #1717	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure.	FY 2017 payment determination and subsequent years.	FY 2014 IPPS/LTCH PPS final rule.
NQF #2512	All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals**.	FY 2017 payment determination and subsequent years**.	FY 2014 IPPS/LTCH PPS final rule.
Application of NQF #0674.	Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).	FY 2018 payment determination and subsequent years**.	FY 2014 IPPS/LTCH PPS final rule.
NQF #2631*	Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	FY 2018 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.
NQF #2632*	Functional Status Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support.	FY 2018 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.
Not NQF endorsed.	National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.	FY 2018 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.

*Endorsed on July 23, 2015. We refer readers to: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867,* NQF #2631 and NQF #2632.

**Adopted in this FY 2016 IPPS/LTCH PPS final rule for the FY 2018 payment determination and subsequent years.

As discussed in sections VIII.C.6.a. through c. of the preamble of this final rule, we are finalizing our proposal to use three previously finalized quality measures in the LTCH QRP for the FY 2018 payment determination and subsequent years. We are finalizing our proposal to use two of these measures in order to establish their use as cross-setting measures that satisfy the required addition of quality measures under the domains of skin integrity and incidence of major falls, as mandated by section 1899B of the Act, as added by the IMPACT Act: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). We are finalizing our proposal to use a third previously finalized measure, All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs (NQF #2512), in order to establish the newly NQF-endorsed status of this measure.

Finally, as discussed in sections VIII.C.6.d. of the preamble of this final rule, for the FY 2018 payment determination and subsequent years, we are finalizing our proposal to add one new cross-setting functional status process measure quality measure to the LTCH QRP: An application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015). This measure satisfies the addition of a quality measure under the third initially

required domain of functional status, as mandated by section 1899B of the Act as added by the IMPACT Act.

Six of the measures being retained in this FY 2016 IPPS/LTCH PPS final rule are currently collected via the CDC NHSN. The NHSN is a secure, Internet-based HAI tracking system maintained and managed by the CDC. NHSN data collection occurs via a Web-based tool hosted by the CDC and provided free of charge to facilities. In this final rule, we have not adopted any new quality measures that are collected via the CDC's NHSN. Therefore, at this time, there is no additional burden related to this submission method. Any burden related to NHSN-based quality measures we have retained in this final rule, has been previously discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445), and has been previously approved under OMB control number 0920–0666, with an expiration date of November, 31, 2016.

The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), which we have finalized in this final rule, is a Medicare FFS claims-based measure. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional information collection will be required from the LTCHs.

The remaining 6 measures will be collected utilizing the LTCH CARE Data Set. The LTCH CARE Data Set, in its current form (version 2.01), has been approved under OMB control number 0938–1163. Version 2.01 of the LTCH CARE Data Set contains data elements related to patient demographic data, various voluntary questions, as well as data elements related to the following quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)
- Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680)

The LTCH CARE Data Set Version 3.00 is available for download at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html* and contains those data elements included in version 2.01, as well as additional data elements in order to allow for the collection of data associated with the following quality measures:

- Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule)
- Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule)
- Functional Status Outcome Measure: Change in Mobility Among LTCH Patients Requiring Ventilator Support (NQF #2632, endorsed on 07/23/2015) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule)

Each time we add new data elements to the LTCH CARE Data Set related to newly proposed or finalized LTCH QRP quality measures, we are required by the Paperwork Reduction Act (PRA) to submit the expanded data collection instrument to OMB for review and approval. Section 1899B(m) of the Act, as added by IMPACT Act, provides that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in subsection 1899B(a)(2)(B) of the Act that require modifications in order to achieve the standardization of patient assessment data. We believe that version 3.00 of the LTCH CARE Data Set falls under the PRA provisions in 1899B(m) of the Act. We believe that all additional data elements added to version 3.00 of the LTCH CARE Data Set are for the purpose of standardizing patient assessment data, as required under section 1899B(a)(1)(B) of the Act.

A comprehensive list of all data elements included in version 3.00 of the LTCH CARE Data Set will be made available in the LTCH QRP Manual, as will be a change table outlining the differences between version 2.01 and version 3.00 of the LTCH CARE Data Set. The LTCH QRP Manual is accessible on the following LTCH Quality Reporting Measures Information Web page: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*. For a discussion of burden related to version 3.00 of the LTCH CARE Data Set, we refer readers to section I.M. of Appendix A of this final rule.

While the reporting of quality measures is an information collection, the PRA does not apply in accordance with the amendments to the Act made by IMPACT Act. More specifically, section 1899B(m) of the Act provides that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in subsection 1899B(a)(2)(B) of the Act that require modifications in order to achieve the standardization of patient assessment data.

We did not receive public comments specific to this section of the FY 2016 IPPS/LTCH PPS proposed rule. However, we did receive several public comments related to the burden associated with specific proposed quality measures. Those comments and our responses are found in sections VIII.C.6.a. through VIII.C.6.d. of the preamble of this final rule.

10. ICRs for the Electronic Health Record (EHR) Incentive Program and Meaningful Use

In section VIII.D. of the preamble of this final rule, we discuss our proposals to align the Medicare EHR Incentive Program reporting and submission timelines for electronically submitted clinical quality measures for eligible hospitals and CAHs with the Hospital IQR Program's reporting and submission timelines for 2016. Because these proposals for data collection which we are finalizing in this final rule will align with the reporting requirements in place for the Hospital IQR Program and eligible hospitals and CAHs still have the option to submit their clinical quality measures via attestation for the Medicare EHR Incentive Program, we do not believe there is any additional burden for this collection of information.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Public Law 106–113 (113 Stat. 1501A–332), sec. 1206 of Public Law 113–67, and sec. 112 of Public Law 113–93.

■ 2. Section 412.23 is amended by—
■ a. In paragraph (e)(3)(i), removing the cross-reference ''paragraphs (e)(3)(ii) through (v)'' wherever it appears and adding in its place the cross-reference ''paragraphs (e)(3)(ii) through (vi)''.
■ b. Adding new paragraph (e)(3)(vi).
■ c. Revising paragraph (e)(6)(ii) introductory text.

The addition and revision reads as follows:

§ 412.23 Excluded hospitals: Classifications.

* * * * *

(e) * * *

(3) * * *

(vi) For cost reporting periods beginning on or after October 1, 2015, the Medicare inpatient days and discharges that are paid at the site neutral payment rate specified at § 412.522(c)(1) or paid under a Medicare Advantage plan (Medicare Part C) will not be included in the calculation of the Medicare inpatient average length of stay specified under paragraph (e)(2)(i) of this section. The provisions of this paragraph (e)(3)(vi) only apply to a hospital that is classified as of December 10, 2013, as a long-term care hospital (as defined in this section) for purposes of determining whether the requirements of paragraph (e)(2)(i) or (e)(2)(ii) of this section are met.

* * * * *

(6) * * *

(ii) *Exception.* The moratorium specified in paragraph (e)(6)(i) of this section is not applicable to the establishment and classification of a long-term care hospital that meets the requirements of paragraphs (e) introductory text and (e)(1) through (e)(5) of this section, or a long-term care hospital satellite facility that meets the requirements of § 412.22(h), if the long-term care hospital or long-term care satellite facility meets one or more of the following criteria on or before December 27, 2007, or prior to April 1, 2014, as applicable:

* * * * *

■ 3. Section 412.64 is amended by revising paragraphs (d)(1)(vi), (h)(4) introductory text, and (h)(4)(vi) introductory text, to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(vi) For fiscal years 2015 and 2016, 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 0.2 percentage point.

* * * * *

(h) * * *

(4) For discharges on or after October 1, 2004 and before October 1, 2016, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

* * * * *

(vi) For discharges on or after October 1, 2012 and before October 1, 2016, the minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

* * * * *

■ 4. Section 412.101 is amended by revising paragraphs (b)(2)(i), (b)(2)(ii), (c)(1), (c)(2) introductory text, and (d) to read as follows:

§ 412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

* * * * *

(b) * * *

(2) * * *

(i) For FY 2005 through FY 2010 and FY 2018 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 2017, 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.

* * * * *

(c) * * *

(1) For FY 2005 through FY 2010 and FY 2018 and subsequent fiscal years, the adjustment is an additional 25 percent for each Medicare discharge.

(2) For FY 2011 through FY 2017, the adjustment is as follows:

* * * * *

(d) *Eligibility of new hospitals for the adjustment.* For FYs 2005 through 2010 and FY 2018 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 under paragraph (b)(2) of this section.

■ 5. Section 412.106 is amended by revising paragraph (g)(1)(iii)(C) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) For fiscal years 2014 and 2015, CMS will base its estimates of the amount of hospital uncompensated care on the most recent available data on utilization for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section. For fiscal year 2016, 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 (b)(4) of this section, using data on Medicaid utilization from 2012 or 2011 cost reports from the most recent HCRIS database extract, the 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available data on Medicare SSI utilization.

* * * * *

§ 412.108 [Amended]

■ 6. In § 412.108, paragraph (a)(1) introductory text and paragraph (c)(2)(iii) introductory text, remove the date ''April 1, 2015'' and add in its place the date ''October 1, 2017''.

■ 7. Section 412.503 is amended by adding a definition of ''Subsection (d) hospital'' in alphabetical order, to read as follows:

§ 412.503 Definitions.

* * * * *

Subsection (d) hospital means, for purposes of § 412.526, a hospital defined in section 1886(d)(1)(B) of the Social Security Act and includes any hospital that is located in Puerto Rico and that would be a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Social Security Act if it were located in one of the 50 States.

* * * * *

■ 8. Section 412.507 is revised to read as follows:

§ 412.507 Limitation on charges to beneficiaries.

(a) *Prohibited charges.* Except as provided in paragraph (b) of this section, a long-term care hospital may not charge a beneficiary for any covered

services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment system. If Medicare has paid at the full LTCH prospective payment system standard Federal payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier threshold is met. If Medicare pays less than the full LTCH prospective payment system standard Federal payment rate and payment was not made at the site neutral payment rate, that payment only applies to the hospital's costs for those costs or days used to calculate the Medicare payment. If Medicare has paid at the full site neutral payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier is met.

(b) *Permitted charges.* (1) A long-term care hospital that receives a payment at the full LTCH prospective payment system standard Federal payment rate or the site neutral payment rate may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, and for items and services as specified under § 489.20(a) of this chapter.

(2) A long-term care hospital that receives a payment at less than the full LTCH prospective payment system standard Federal payment rate for a short-stay outlier case, in accordance with § 412.529 (which would not include any discharge paid at the site neutral payment rate), may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, for items and services as specified under § 489.20(a) of this chapter, and for services provided during the stay that were not the basis for the short-stay adjusted payment.

■ 9. Section 412.517 is amended by adding paragraph (c) to read as follows:

§ 412.517 Revision of LTC–DRG group classifications and weighting factors.

* * * * *

(c) Beginning in FY 2016, the annual recalibration of the weighting factors described in paragraph (a) of this section is determined using long-term care hospital discharges described in § 412.522(a)(2) (or that would have been described in such section had the application of the site neutral payment rate been in effect at the time of the discharge).

■ 10. Section 412.521 is amended by revising paragraph (a)(2) to read as follows:

§ 412.521 Basis of payment.

(a) * * *

(2) Except as provided for in § 412.526, the amount of payment under the prospective payment system is based on either the long-term care hospital prospective payment system standard Federal payment rate established in accordance with § 412.523, including adjustments described in § 412.525, or the site neutral payment rate established in accordance with § 412.522(c), or, if applicable during a transition period, the blend of the LTCH PPS standard Federal payment rate and the applicable site neutral payment rate described in § 412.522(c)(3).

* * * * *

■ 11. Section 412.522 is added to read as follows:

§ 412.522 Application of site neutral payment rate.

(a) *General.* For discharges in cost reporting periods beginning on or after October 1, 2015—

(1) Except as provided for in paragraph (b) of this section, all discharges are paid based on the site neutral payment rate as determined under the provisions of paragraph (c) of this section.

(2) Discharges that meet the criteria for exclusion from site neutral payment rate specified in paragraph (b) of this section are paid based on the standard Federal prospective payment rate established under § 412.523.

(b) *Criteria for exclusion from the site neutral payment rate*—(1) *General.* A discharge that meets the following criteria is excluded from the site neutral payment rate specified under this section.

(i) The discharge from the long-term care hospital does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation based on the LTC–DRG assignment of the discharge under § 412.513; and

(ii) The admission to the long-term care hospital was immediately preceded by a discharge from a subsection (d) hospital and meets either the intensive care unit criterion specified in paragraph (b)(2) of this section or the ventilator criterion specified in paragraph (b)(3) of this section. In order for an admission to a long-term care hospital to be considered immediately preceded for purposes of this section, the patient discharged from the subsection (d) hospital must be directly admitted to the long-term care hospital.

(2) *Intensive care unit criterion.* In addition to meeting the requirements of paragraph (b)(1) of this section, the discharge from the subsection (d) hospital that immediately preceded the admission to the long-term care hospital includes at least 3 days in an intensive care unit (as defined in § 413.53(d) of this chapter), as evidenced by at least one of the revenue center codes on the claim for the discharge that indicate such services were provided for the requisite number of days during the stay.

(3) *Ventilator criterion.* In addition to meeting the requirements of paragraph (b)(1) of this section, the discharge from the long-term care hospital is assigned to a LTC–DRG based on the patient's receipt of ventilator services of at least 96 hours, as evidenced by the procedure code on the discharge bill indicating such services were provided during the stay.

(c) *Site neutral payment rate*—(1) *General.* Subject to the provisions of paragraph (c)(2) of this section, the site neutral payment rate is the lower of—

(i) The inpatient hospital prospective payment system comparable per diem amount determined under § 412.529(d)(4), including any applicable outlier payments specified in § 412.525(a); or

(ii) 100 percent of the estimated cost of the case determined under the provisions of § 412.529(d)(2). The provisions for cost-to-charge ratios at § 412.529(f)(4)(i) through (iii) apply to the calculation of the estimated cost of the case under this paragraph.

(2) *Adjustments.* CMS adjusts the payment rate determined under paragraph (c)(1) of this section to account for—

(i) Outlier payments, by applying a reduction factor equal to the estimated proportion of outlier payments under § 412.525(a) payable for discharges from a long-term care hospital described in paragraph (a)(1) of this section to total estimated payments under the long-term care hospital prospective payment system to discharges from a long-term care hospital described in paragraph (a)(1) of this section. The adjustment under this paragraph (c)(2)(i) does not include the portion of the blended payment rate described in paragraph (c)(3)(ii) of this section.

(ii) A 3-day or less interruption of a stay and a greater than 3-day interruption of a stay, as provided for in § 412.531. For purposes of the application of the provisions of § 412.531 to discharges from a long-term care hospital described under paragraph (a)(1) of this section, the long-term care hospital prospective payment system

standard Federal payment-related terms, such as ''LTC–DRG payment,'' ''full Federal LTC–DRG prospective payment,'' and ''Federal prospective payment,'' mean the site neutral payment rate calculated under paragraph (c) of this section.

(iii) The special payment provisions for long-term care hospitals-within-hospitals and satellite facilities of long-term care hospitals specified in § 412.534.

(iv) The special payment provisions for long-term care hospitals and satellite facilities of long-term care hospitals that discharged Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite facility of the long-term care hospital, as provided in § 412.536.

(3) *Transition.* For discharges in cost reporting periods beginning on or after October 1, 2015 and on or before September 30, 2017, payment for discharges under paragraph (c)(1) of this section are made using a blended payment rate, which is determined as—

(i) 50 percent of the site neutral payment rate amount for the discharge as determined under paragraph (c)(1) of this section; and

(ii) 50 percent of the standard Federal prospective payment rate amount for the discharge as determined under § 412.523.

(d) *Discharge payment percentage.* (1) For purposes of this section, the discharge payment percentage is a ratio, expressed as a percentage, of Medicare discharges that meet the criteria for exclusion from the site neutral payment rate as described under paragraph (a)(2) of this section to total Medicare discharges paid under this subpart during the cost reporting period.

(2) CMS will inform each long-term care hospital of its discharge payment percentage, as determined under paragraph (d)(1) of this section, for each cost reporting period beginning on or after October 1, 2015.

■ 12. Section 412.523 is amended by adding paragraph (c)(3)(xii) and revising paragraph (d)(1) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2015, and ending September 30, 2016.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2015, and ending September 30, 2016, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.7 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

(d) * * *

(1) *Outlier payments.* CMS adjusts the LTCH PPS standard Federal payment rate by a reduction factor of 8 percent, the estimated proportion of outlier payments under § 412.525(a) payable for discharges described in § 412.522(a)(2).

* * * * *

■ 13. Section 412.525 is amended by revising paragraphs (a)(1), (2), and (3) and adding paragraph (a)(5), to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

(a) * * *

(1) CMS provides for an additional payment to a long-term care hospital if its estimated costs for a patient exceed the applicable long-term care hospital prospective payment system payment plus an applicable fixed-loss amount. For each long-term care hospital prospective payment system payment year, CMS annually establishes a fixed-loss amount that is the maximum loss that a long-term care hospital would incur under the long-term care hospital prospective payment system for a case with unusually high costs before receiving an additional payment.

(2) The fixed-loss amount for discharges from a long-term care hospital described under § 412.522(a)(2) is determined for the long-term care hospital prospective payment system payment year, using the LTC–DRG relative weights that are in effect at the start of the applicable long-term care hospital prospective payment system payment year.

(3) The additional payment equals 80 percent of the difference between the estimated cost of the patient's care (determined by multiplying the hospital-specific cost-to-charge ratio by the Medicare allowable covered charge) and the sum of the applicable long-term care hospital prospective payment system payment and the applicable fixed-loss amount.

* * * * *

(5) For purposes of this paragraph (a)—

(i) *Applicable long-term care hospital prospective payment system payment* means—

(A) The site neutral payment rate established under § 412.522(c) for long-term care hospital discharges described under § 412.522(a)(1);

(B) The standard Federal prospective payment rates established under § 412.523 for long-term care hospital discharges described under § 412.522(a)(2); or

(C) The standard Federal prospective payment rates established under § 412.523 for discharges occurring on or after October 1, 2015, in a long-term care hospital cost reporting period that begins before October 1, 2015.

(ii) *Applicable fixed-loss amount* means—

(A) For long-term care hospital discharges described under § 412.522(a)(1), the fixed-loss amount established for such cases as provided at § 412.522(c)(2)(i);

(B) For long-term care hospital discharges described under § 412.522(a)(2), the fixed-loss amount established for such cases as provided at § 412.523(e); or

(C) For discharges occurring on or after October 1, 2015 in a long-term care hospital cost reporting period that begins before October 1, 2015, the fixed-loss amount payable to discharges described under § 412.522(a)(2) as set forth in paragraph (a)(5)(ii)(B) of this section.

* * * * *

■ 14. Section § 412.560 is added to subpart O to read as follows:

§ 412.560 Participation, data submission, and other requirements under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program.

(a) *Participation in the LTCHQR Program.* A long-term-care hospital must begin submitting quality data under the LTCHQR Program by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter.

(b) *Submission of data requirements and payment impact.* (1) Except as provided in paragraph (c) of this section, a long-term care hospital must submit to CMS data on measures specified under sections 1886(m)(5)(D), 1899B(c)(1), and 1899B(d)(1) of the Act, as applicable, in a form and manner, and at a time, specified by CMS.

(2) A long-term care hospital that does not submit data in accordance with sections 1886(m)(5)(C) and 1886(m)(5)(F) of the Act with respect to a given fiscal year will have its annual update to the standard Federal rate for discharges for the long-term care hospital during the fiscal year reduced by 2 percentage points.

(c) *Exception and extension request requirements.* Upon request by a long-term care hospital, CMS may grant an exception or extension with respect to

the quality data reporting requirements, for one or more quarters, in the event of certain extraordinary circumstances beyond the control of the long-term care hospital, subject to the following:

(1) A long-term care hospital that wishes to request an exception or extension with respect to quality data reporting requirements must submit its request to CMS within 30 days of the date that the extraordinary circumstances occurred.

(2) A long-term care hospital must submit its request for an exception or extension to CMS via email. Email is the only form that may be used to submit to CMS a request for an exception or an extension.

(3) The email request for an exception or extension must contain the following information:

(i) The CCN for the long-term care hospital.

(ii) The business name of the long-term care hospital.

(iii) The business address of the long-term care hospital.

(iv) Contact information for the long-term care hospital's chief executive officer or designated personnel, including the name, telephone number, title, email address, and physical mailing address. (The mailing address may not be a post office box.)

(v) A statement of the reason for the request for the exception or extension.

(vi) Evidence of the impact of the extraordinary circumstances, including, but not limited to, photographs, newspaper articles, and other media.

(vii) The date on which the long-term care hospital will be able to again submit quality data under the LTCHQR Program and a justification for the proposed date.

(4) CMS may grant an exception or extension to a long-term care hospital that has not been requested by the long-term care hospital if CMS determines that—

(i) An extraordinary circumstance affects an entire region or locale; or

(ii) A systemic problem with one of CMS' data collection systems directly affected the ability of the long-term care hospital to submit quality data.

(d) *Reconsiderations of noncompliance decisions*—(1) *Written notification of noncompliance decision.* CMS will send a long-term care hospital written notification of a decision of noncompliance with the quality data reporting requirements for a particular fiscal year. CMS also will use the Quality Improvement and Evaluation system (QIES) Assessment Submission and Processing (ASAP) System to provide notification of noncompliance to the long-term care hospital.

(2) *Request for reconsideration of noncompliance decision.* A long-term care hospital may request a reconsideration of CMS' decision of noncompliance no later than 30 calendar days from the date of the written notification of noncompliance. The reconsideration request by the long-term care hospital must be submitted to CMS via email and must contain the following information:

(i) The CCN for the long-term care hospital.

(ii) The business name of the long-term care hospital.

(iii) The business address of the long-term care hospital.

(iv) Contact information for the long-term care hospital's chief executive officer or designated personnel, including each individual's name, title, email address, telephone number, and physical mailing address. (The physical address may not be a post office box.)

(v) CMS's identified reason(s) for the noncompliance decision from the written notification of noncompliance.

(vi) The reason for requesting reconsideration of CMS' noncompliance decision.

(vii) Accompanying documentation that demonstrates compliance of the long-term care hospital with the quality reporting requirements. This documentation must be submitted electronically at the same time as the reconsideration request as an attachment to the email. Any reconsideration request that fails to provide sufficient evidence of compliance will not be reviewed.

(3) *CMS decision on reconsideration request.* CMS will notify the long-term care hospital, in writing, of its final decision regarding any reconsideration request. CMS also will use the QIES ASAP System to provide notice of its final decision on the reconsideration request.

(e) *Appeals of reconsideration requests.* A long-term care hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under Part 405, Subpart R, of this chapter.

Dated: July 27, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 29, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning On or After October 1, 2015, and Payment Rates for LTCHs Effective for Discharges Occurring On or After October 1, 2015

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2016 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 2016. 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 figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that are effective for cost reporting periods beginning on or after October 1, 2015.

In addition, we are setting forth a description of the methods and data we used to determine the standard Federal rate that will be applicable to Medicare LTCHs for FY 2016.

In general, except for SCHs, MDHs, and hospitals located in Puerto Rico, for FY 2016, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (including, as discussed in section IV.D. of the preamble of this final 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.

We note that 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).

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.

For hospitals located in Puerto Rico, the payment per discharge is based on the sum of 25 percent of an updated Puerto Rico-specific rate based on average costs per case of Puerto Rico hospitals for the base year and 75 percent of the Federal national rate. (We refer readers to section II.D.2. of this Addendum for a complete description.)

As discussed in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2016. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2016. 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 2016. In section V. of this Addendum, we discuss policy changes for determining the standard Federal rate for LTCHs paid under the LTCH PPS for FY 2016. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the Internet on the CMS Web site.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2016

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 42 CFR 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 42 CFR 412.211 and 412.212. Below we discuss the factors we are using for determining the prospective payment rates for FY 2016.

In summary, the 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 Web site) 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 and Puerto Rico-specific 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 2016, 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.A. of the preamble of this final rule for a complete discussion on the FY 2016 inpatient hospital update. Below is a table with these four options:

FY 2016	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
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.6	−0.6
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−1.2	0.0	−1.2
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Applicable Percentage Increase Applied to Standardized Amount	1.7	0.5	1.1	−0.1

- An update of 1.7 percent to the Puerto Rico-specific standardized amount (that is, the FY 2016 estimate of the market basket rate-of-increase of 2.4 percent less an adjustment of 0.5 percentage point for MFP and less 0.2 percentage point), in accordance with section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Public Law 108–173, which sets the update to the Puerto Rico-specific standardized amount equal to the applicable percentage increase set forth under section 1886(b)(3)(B)(i) of the Act.
- 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 changes are budget neutral, as

provided for under section 1886(d)(3)(E)(i) of the Act. 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 2015 budget neutrality factor and applying a revised factor.
- As discussed below and in section III.G. of the preamble of this final rule, an adjustment to offset the cost of the 3-year hold harmless transitional wage index provisions provided by CMS as a result of the implementation of the new OMB labor market area delineations (beginning with FY 2015).
- 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, are budget neutral as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to remove the FY 2015 outlier offset and apply an offset for FY 2016, as provided for under section 1886(d)(3)(B) of the Act.
- As discussed below and in section II.D. of the preamble of this final rule, a recoupment to meet the requirements of section 631 of the ATRA to adjust the standardized amount to offset the estimated 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.

For FY 2016, consistent with current law, we are applying 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 applying a uniform, national budget neutrality adjustment to the FY 2016 wage index for the rural floor. We note that, in section III.G.2.b. of the preamble to this final rule, we are extending the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2016. Therefore, for FY 2016, in this final rule, we are continuing to include the imputed floor (calculated under the original and alternative methodologies) in calculating the uniform, national rural floor budget neutrality adjustment, which are reflected in the FY 2016 wage index.

A. Calculation of the 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. For Puerto Rico hospitals, the Puerto Rico-specific standardized amount is based on per discharge averages of adjusted target amounts from a base period (section 1886(d)(9)(B)(i) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d)(9) 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. The September 1, 1987 final rule (52 FR 33043 and 33066) contains a detailed explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

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 2016, we are continuing to use the national and Puerto Rico-specific labor-related and nonlabor-related shares (which are based on the FY 2010-based hospital market basket) that were used in FY 2015. 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 2016, as discussed in section III. of the preamble of this final rule, we are continuing to use a labor-related share of 69.6 percent for the national standardized amounts, and 63.2 percent for the Puerto Rico-specific standardized amount, if the hospital has a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals whose wage index values are less than or equal to 1.0000. For all IPPS hospitals whose wage indexes are greater than 1.0000, we are applying the wage index to a labor-related share of 69.6 percent of the national standardized amount.

For FY 2016, all Puerto Rico hospitals have a wage index value that is less than 1.0000 because the average hourly rate of every hospital in Puerto Rico divided by the national average hourly rate (the sum of all salaries and hours for all hospitals in the 50 United States and Puerto Rico) results in a wage index that is below 1.0000. However, when we divide the average hourly rate of every hospital located in Puerto Rico by the Puerto Rico-specific national average hourly rate (the sum of all salaries and hours for all hospitals located only in Puerto Rico), the result is a Puerto Rico-specific wage index value for some hospitals that is either above, or below 1.0000, depending on the hospital's location within Puerto Rico. Therefore, for hospitals located in Puerto Rico, we are applying a labor-related share of 63.2 percent if its Puerto Rico-specific wage index is greater than 1.0000. For hospitals located in Puerto Rico whose Puerto Rico-specific wage index values are less than or equal to 1.0000, we are applying a labor share of 62 percent.

The 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 final rule and are available via the Internet on the CMS Web site.

2. Computing the National Average Standardized Amount and Puerto Rico-Specific 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. Section 1886(d)(9)(A)(ii)(II) of the Act equalizes the Puerto Rico-specific urban and rural area rates. Accordingly, we are calculating the FY 2016 national average standardized amount and Puerto Rico-specific standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount and Puerto Rico-Specific 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 final rule, we are using the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2016 (which replaced the FY 2006-based IPPS operating and capital market baskets in FY 2014). As discussed in section IV.A. of the preamble of this final 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 reducing the FY 2016 applicable percentage increase (which is based on IHS Global Insight, Inc.'s (IGI's) second quarter 2015 forecast of the FY 2010-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2016) of 0.5 percentage point, which is calculated based on IGI's second quarter 2015 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 further updating the standardized amount for FY 2016 by the estimated market basket percentage increase less 0.2 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 comprising routine, ancillary, and special care unit hospital inpatient services.

Based on IGI's 2015 second quarter forecast of the hospital market basket increase (as discussed in Appendix B of this final rule), the most recent forecast of the hospital market basket increase for FY 2016 is 2.4 percent. As discussed above, for FY 2016, 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 could be applied to the standardized amount. We refer readers to section IV.A. of the preamble of this final rule for a complete discussion on the FY 2016 inpatient hospital update to the standardized amount. We also refer readers to the table above for the four possible applicable percentage increases that are applied to update the national standardized amount. The 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 Web site reflect these differential amounts.

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth under section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are establishing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.7 percent for FY 2016.

Although the update factors for FY 2016 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 2016 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 proposed recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this final rule.

4. Other Adjustments to the Average Standardized Amount

As in the past, we are adjusting the FY 2016 standardized amount to remove the effects of the FY 2015 geographic reclassifications and outlier payments before applying the FY 2016 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on finalized FY 2016 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.

In order to appropriately estimate aggregate payments in our modeling, we make several inclusions and exclusions so that the appropriate universe of claims and charges are included. We discuss IME Medicare Advantage payment amounts, fee-for-service only claims, and charges for anti-hemophilic blood factor and organ acquisition below.

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.

In addition, 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 a fee-for-service claim).

Finally, consistent with our methodology established in the FY 2011

IPPS/LTCH PPS final rule (75 FR 50422 through 50423), 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 for the budget neutrality adjustments. We also removed organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

The Bundled Payments for Care Improvement (BPCI) initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. On January 31, 2013, CMS announced the first set of health care organizations selected to participate in the BPCI initiative. Additional organizations were selected in 2014. For additional information on the BPCI initiative, we refer readers to the CMS Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html*.

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 2016, we are continuing to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations.

The Affordable Care Act established the Hospital Readmissions Reduction Program and the Hospital VBP Program which adjust payments to certain IPPS hospitals beginning with discharges on or after October 1, 2012. Because the adjustments made under these programs affect the estimation of aggregate IPPS payments, in this final rule, 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 these programs within our budget neutrality calculations. We discuss the treatment of these two programs in the context of budget neutrality adjustments below.

Section 1886(q) of the Act establishes the ''Hospital Readmissions Reduction Program'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act are reduced to account for certain excess readmissions. Under the Hospital Readmissions Reduction Program, for discharges beginning on October 1, 2012 discharges from an ''applicable hospital'' are paid at an amount equal to the product of the ''base operating DRG payment amount'' and an ''adjustment factor'' that accounts for excess readmissions for the hospital for the fiscal year plus any applicable add-on payments. We refer readers to section IV.E. of the preamble of this final rule for full details of our FY 2016 policy changes to the Hospital Readmissions Reduction Program. We also note that the Hospital Readmissions Reduction Program provided for under section 1886(q) of the Act is not budget neutral.

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which, for discharges beginning on October 1, 2012, value-based incentive payments are made in a fiscal year to eligible subsection (d) hospitals based on their performance on measures established for a performance period for that fiscal year. As specified under section 1886(o)(7)(B)(i) of the Act, these value-based incentive payments are funded by a reduction applied to each eligible hospital's base-operating DRG payment amount, for each discharge occurring in the fiscal year. As required by section 1886(o)(7)(A) of the Act, the total amount of allocated funds available for value-based incentive payments with respect to a fiscal year is equal to the total amount of base-operating DRG payment reductions, as estimated by the Secretary. In a given fiscal year, hospitals may earn a value-based incentive payment amount for a fiscal year that is greater than, equal to, or less than the reduction amount, based on their performance on quality measures under the Hospital VBP Program. Thus, the Hospital VBP Program is estimated to have no net effect on overall payments. We refer readers to section IV.F. of the preamble of this final rule for details regarding the Hospital VBP Program.

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. For example, when we calculate the budget neutrality factor for MS–DRG reclassification and recalibration of the relative weights, we compare aggregate payments estimated using the prior year's GROUPER and relative weights to estimated payments using the new GROUPER and relative weights. (We refer readers to section II.A.4.a. of this Addendum for details.) Other factors, such as the DSH and IME payment adjustments, are the same on both sides of the comparison because we are only seeking to ensure that aggregate payments do not increase or decrease as a result of the changes of MS–DRG reclassification and recalibration.

In order to properly determine aggregate payments on each side of the comparison, as we did for FY 2014 and FY 2015, for FY 2016 and subsequent years, we are continuing to apply the hospital readmissions payment adjustment and the 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 applying the readmissions payment adjustment factor and the 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 FY 2016 readmissions payment adjustment factors, we are using excess readmission ratios and aggregate payments for excess readmissions based on admissions from the prior fiscal year's applicable period because hospitals have had the opportunity to review and correct these data before the data were made public under the policy we adopted regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. For FY 2016, in this final rule, we are calculating the readmissions payment adjustment factors using excess readmission ratios and aggregate payments for excess readmissions based on admissions from the finalized applicable period for FY 2016 as hospitals have had the opportunity to review and correct these data under our

policy regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act. We discuss our policy regarding the reporting of hospital-specific readmission rates for FY 2016 in section IV.E.3.f. of the preamble of this final rule. (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).)

In addition, for FY 2016, in this final rule, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we are using proxy hospital VBP payment adjustment factors for FY 2016 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 2016 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 will 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 under age 65 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 2016 (as we did for FY 2014 and FY 2015), we are including 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 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.

We note that, 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.D. of the preamble to this final rule and below, we are continuing 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 include estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV. of the preamble to this final 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 continuing to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

In addition, we are including 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 2016. We did not include this adjustment for FY 2015 because that was the first year hospitals experienced a reduction to their applicable percentage increase due to whether they are meaningful EHR users and data were not available at that time. However, we believe it is appropriate to include this adjustment for FY 2016 because FY 2016 is the second year for which hospitals will experience this reduction and data on the prior year's performance are now available. Payments for hospitals are estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2016.

a. Recalibration of MS–DRG Relative Weights and Updated Wage Index—Budget Neutrality Adjustment

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.H. of the preamble of this final 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 making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

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 2016, we are adjusting 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 final rule.

For FY 2016, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the Puerto Rico standardized amount and the hospital-specific rates, we used FY 2014 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2015 labor-related share percentages, the FY 2015 relative weights, and the FY 2015 pre-reclassified wage data, and applied the FY 2016 hospital readmissions payment adjustments and estimated FY 2016 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2015 labor-related share percentages, the FY 2016 relative weights, and the FY 2015 pre-reclassified wage data, and applied the same FY 2016 hospital readmissions payment adjustments and estimated FY 2016 hospital VBP payment adjustments applied above.

Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.998399. As discussed in section IV. of this Addendum, we also are applying the MS–DRG reclassification and recalibration budget neutrality factor of 0.998399 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2015.

In order to meet the statutory requirements that we do not take into account the labor-related share of 62 percent when computing wage index budget neutrality adjustment factor, it was necessary to use a three-step process to comply with the requirements that MS–DRG reclassification and recalibration of the relative weights and the updated wage index and labor-related share have no effect on aggregate payments for IPPS hospitals. Under the first step, we determined an MS–DRG reclassification and recalibration budget neutrality adjustment factor of 0.998399 (by using the same methodology described above to determine the MS–DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates). Under the second step, to compute a budget neutrality adjustment factor for wage index and labor-related share percentage changes we used FY 2014 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2016 relative weights and the FY 2015 pre-reclassified wage indexes, applied the FY 2015 labor-related share of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the FY 2016 hospital readmissions payment adjustment and the estimated FY 2016 hospital VBP payment adjustment; and
- Aggregate payments using the FY 2016 relative weights and the FY 2016 pre-reclassified wage indexes, applied the labor-related share for FY 2016 of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same FY 2016 hospital readmissions payment adjustments and estimated FY 2016 hospital VBP payment adjustments applied above.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2015 to FY 2016. By applying this methodology, we determined a budget neutrality adjustment factor of 0.998749 for changes to the wage index. Finally, we multiplied the MS–DRG reclassification and recalibration budget neutrality adjustment factor of 0.998399 (derived in the first step) by the budget neutrality adjustment factor of 0.998749 for changes to the wage index (derived in the second step) to determine the MS–DRG reclassification and recalibration and updated wage index budget neutrality adjustment factor of 0.997150.

b. Reclassified Hospitals—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 budget neutrality adjustment factor for FY 2016, we used FY 2014 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2016 labor-related share percentages, FY 2016 relative weights, and FY 2016 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the FY 2016 hospital readmissions payment adjustments and the estimated FY 2016 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2016 labor-related share percentages, FY 2016 relative weights, and FY 2016 wage data after such reclassifications, and applied the same FY 2016 hospital readmissions payment adjustments and the estimated FY 2016 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 final rule, which is available via the Internet on the CMS Web site. This table reflects reclassification crosswalks for FY 2016, and applies the policies explained in section III. of the preamble to this final rule. Based on these simulations, we calculated a budget neutrality adjustment factor of 0.987905 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The FY 2016 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2015 budget neutrality adjustment factor. We note that the FY 2016 budget neutrality adjustment reflects FY 2016 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of the final rule.

c. 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) and the imputed floor under § 412.64(h)(4) are equal to the aggregate prospective payments that would have

been made in the absence of such provisions. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.H. of the preamble of this final rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural and imputed floor is a national adjustment to the wage index.

As noted above and as discussed in section III.H.2. of the preamble of this final rule, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51594), we extended the imputed floor calculated under the original methodology through FY 2013. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we established an alternative methodology for calculating the imputed floor and established a policy that the minimum wage index value for an all-urban State would be the higher of the value determined under the original methodology or the value computed using the alternative methodology. Consistent with the methodology for treating the imputed floor, similar to the methodology we used in the FY 2013 IPPS/LTCH PPS final rule, we included this alternative methodology for computing the imputed floor index in the calculation of the uniform, national rural floor budget neutrality adjustment for FY 2014. For FY 2015, as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49969 through 49971), we extended the imputed floor for another year using the higher of the value determined under the original methodology or the alternative methodology. As discussed in section III.H.2. of the preamble of this final rule, we are extending the imputed floor using the higher of the value determined under the original methodology or the alternative methodology for FY 2016. Therefore, in order to ensure that aggregate payments to hospitals are not affected, similar to prior years, we follow our policy of including the imputed floor in the rural floor budget neutrality adjustment to the wage index.

Under the new OMB labor market area delineations adopted beginning with the FY 2015 wage indexes, New Jersey, Rhode Island, and Delaware are all-urban States. Therefore, for FY 2016, the imputed floor was applied to the wage index for hospitals located in these three States.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2016, we are calculating a national rural Puerto Rico wage index (used to adjust the labor-related share of the national standardized amount for hospitals located in Puerto Rico which receive 75 percent of the national standardized amount) and a rural Puerto Rico-specific wage index (which is used to adjust the labor-related share of the Puerto Rico-specific standardized amount for hospitals located in Puerto Rico that receive 25 percent of the Puerto Rico-specific standardized amount). Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2016 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 new 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 FY 2016 rural Puerto Rico wage index is calculated based on the average of the FY 2016 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 national rural floor and imputed floor budget neutrality adjustment factors and the Puerto Rico-specific rural floor budget neutrality adjustment factor, we used FY 2014 discharge data to simulate payments and the post-reclassified national and Puerto Rico-specific wage indexes and compared the following:

- The national and Puerto Rico-specific simulated payments without the national rural floor and imputed floor and Puerto Rico-specific rural floor applied; and
- The national and Puerto Rico-specific simulated payments with the national rural floor and imputed floor and Puerto Rico-specific rural floor applied.

Based on this comparison, we determined a national rural budget neutrality adjustment factor of 0.990298 and the Puerto Rico-specific budget neutrality adjustment factor of 0.987646. The national adjustment was applied to the national wage indexes to produce a national rural floor budget neutral wage index and the Puerto Rico-specific adjustment was applied to the Puerto Rico-specific wage indexes to produce a Puerto Rico-specific rural floor budget neutral wage index.

d. Wage Index Transition Budget Neutrality

As discussed in section III.G. of the preamble of this final rule, in the past, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts.

Similar to FY 2005, for FY 2015, we determined that the transition to using the new OMB labor market area delineations would have the largest impact on hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations. To alleviate the decreased payments associated with having a rural wage index, in calculating the area wage index, similar to the transition provided in the FY 2005 IPPS final rule, we finalized a policy to generally assign these counties the urban wage index value of the CBSA to which they are physically located in for FY 2014 for FYs 2015, 2016, and 2017. Fiscal year 2016 is the second year of this 3-year transition policy. We note that the 1-year blended wage index transitional policy for all hospitals that would experience any decrease in their wage index value expires in FY 2015.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), in the past, CMS has budget neutralized transitional wage indexes. We stated that because we established a policy that allows for the application of a transitional wage index only when it benefits the hospital, we believe that it would be appropriate to ensure that such a transitional policy does not increase aggregate Medicare payments beyond the payments that would be made had we simply adopted the OMB delineations without any transitional provisions. Therefore, as we did for FY 2015, for FY 2016, we are using our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to make an adjustment to the national and Puerto Rico-specific standardized amounts to ensure that total payments for the effect of the 3-year transitional wage index provisions will equal what payments would have been if we had fully adopted the new OMB delineations without providing these transitional provisions. To calculate the transitional wage index budget neutrality factor for FY 2016, we used FY 2014 discharge data to simulate payments and compared the following:

- Aggregate payments using the OMB delineations for FY 2016, the FY 2016 relative weights, the FY 2016 wage data after such reclassifications under

sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the rural floor budget neutrality adjustment factor to the wage index, and application of the FY 2016 hospital readmissions payment adjustments and the estimated FY 2016 hospital VBP payment adjustments; and

• Aggregate payments using the OMB delineations for FY 2016, the FY 2016 relative weights, the FY 2016 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the rural floor budget neutrality adjustment factor to the wage index, application of the 3-year transitional wage indexes, and application of the same FY 2016 hospital readmissions payment adjustments and the estimated FY 2016 hospital VBP payment adjustments applied above.

Based on these simulations, we calculated a budget neutrality adjustment factor of 0.999996. Therefore, for FY 2016, we applied a transitional wage index budget neutrality adjustment factor of 0.999996 to the national average and Puerto Rico-specific standardized amounts to ensure that the effects of these transitional wage indexes are budget neutral.

We note that the budget neutrality adjustment factor calculated above is based on the increase in payments in FY 2016 that would result from the second year of the 3-year transitional wage index policies. Therefore, we applied this budget neutrality adjustment factor as a one-time adjustment to the FY 2016 national and Puerto Rico-specific standardized amounts in order to offset the increase in payments in FY 2016 as a result of this second year of the 3-year transitional wage index. For subsequent fiscal years, we will not take into consideration the adjustment factor applied to the national and Puerto Rico-specific standardized amounts in the previous fiscal year's update when calculating the current fiscal year transitional wage index budget neutrality adjustment factor (that is, this adjustment will not be applied cumulatively).

e. Case-Mix Budget Neutrality Adjustment

(1) Background

Below we summarize the recoupment adjustment to the FY 2016 payment rates, as required by section 631 of ATRA, to account for 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. We refer readers to section II.D. of the preamble of this final rule for a complete discussion regarding our policies for FY 2016 in this final rule 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.

(2) Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA) to the National Standardized Amount

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 totaling $11 billion by FY 2017. Our actuaries estimated that if CMS were to fully account for the $11 billion recoupment required by section 631 of the ATRA in FY 2014, a one-time −9.3 percent adjustment to the standardized amount would be necessary. It is often our practice to delay or phase-in payment rate adjustments over more than 1 year, in order to moderate the effect on payment rates in any 1 year. Therefore, consistent with the policies that we have adopted in many similar cases, for FY 2014 and FY 2015, we applied a −0.8 percent adjustment to the standardized amount. For FY 2016, as we proposed, we are applying a −0.8 percent adjustment to the standardized amount. We note that, as section 631 of the ATRA instructs the Secretary to make a recoupment adjustment only to the standardized amount, this adjustment does not apply to the Puerto Rico-specific standardized amount and hospital-specific payment rates.

f. Rural Community Hospital Demonstration Program Adjustment

As discussed in section IV.L. of the preamble of this final rule, section 410A of Public Law 108–173 originally required the Secretary to establish a demonstration program that modifies reimbursement for inpatient services for up to 15 small rural hospitals. 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.

Sections 3123 and 10313 of the Affordable Care Act extended the demonstration program for an additional 5-year period, and allowed up to 30 hospitals to participate in 20 States with low population densities determined by the Secretary. (In determining which States to include in the expansion, the Secretary is required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period.) In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50141 through 50145), in order to achieve budget neutrality, we adjusted the national IPPS payment rates by an amount sufficient to account for the added costs of this demonstration program as described in section IV.L. of that final rule. In other words, we applied budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration program, consistent with past practice. We stated that we believe the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For FY 2016, we are calculating a budget neutrality offset amount, according to the methodology set forth in section IV.I. of the preamble of this final rule, to account for the estimated additional costs of the demonstration program for FY 2016. In addition, as explained in section IV.I. of the preamble of this final rule, we are subtracting from this budget neutrality offset amount the following: (1) The amount by which the budget neutrality offset that was finalized in the FY 2009 IPPS final rule exceeded the actual costs of the demonstration for FY 2009 (as shown in finalized cost reports for hospitals that participated in FY 2009 and had cost reporting periods beginning in FY 2009), and (2) the amount by which the budget neutrality offset that was finalized for FY 2010 to account for the demonstration costs in FY 2010 (as set forth in the FY 2010 and 2011 IPPS final rules) exceeded the actual costs of the demonstration for FY 2010 (as shown in finalized cost reports for hospitals that participated in FY 2010 and had cost reporting periods beginning in FY 2010). The total budget neutrality offset amount for which the adjustment to the FY 2016 IPPS rates is calculated is $12,835,618. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2016, we have computed a factor of 0.999861 for the rural community hospital

demonstration program budget neutrality adjustment that will be applied to the IPPS standard Federal payment rate.

g. 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 DRG, any IME and DSH 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 DRG, any IME and DSH 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 2016 is 80 percent, the same marginal cost factor we have used 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. Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary to reduce the average standardized amount applicable to hospitals located in Puerto Rico 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 Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html.*

(1) FY 2016 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 detailed discussion of the changes.

For FY 2016, we proposed to continue to use the same methodology that we used in FY 2015. As we have done in the past, to calculate the proposed FY 2016 outlier threshold, we simulated payments by applying proposed FY 2016 payment rates and policies using cases from the FY 2014 MedPAR file. Therefore, in order to determine the proposed FY 2016 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2014 to FY 2016. As discussed in the FY 2014 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.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50375), 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, consistent with our longstanding policy since FY 2005, we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. We also stated we would consider how best to provide additional information on the charge inflation factor for future years. In response to those comments, in the proposed rule, we provided the following table that displays covered charges and cases by quarter in the periods used to calculate the charge inflation factor.

Quarter	Covered charges (January 1, 2013, through December 31, 2013)	Cases (January 1, 2013, through December 31, 2013)	Covered charges (January 1, 2014, through December 31, 2014)	Cases (January 1, 2014, through December 31, 2014)
1	$126,534,546,428	2,640,744	$125,988,476,809	2,480,809
2	118,741,812,697	2,507,483	121,297,544,913	2,433,390
3	115,745,380,133	2,425,636	116,785,744,335	2,321,731
4	119,331,676,066	2,406,770	89,923,763,220	1,764,002
Total	480,353,415,324	9,980,633	453,995,529,277	8,999,932

Under this new methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2016, we proposed to compare the average covered charge per case of $48,129 ($480,353,415,324/9,980,633) from the second quarter of FY 2013 through the first quarter of FY 2014 (January 1, 2013, through December 31, 2013) to the average covered charge per case of $50,444 ($453,995,529,277/8,999,932) from the second quarter of FY 2014 through the first quarter of FY 2015 (January 1, 2014, through December 31, 2014). This rate-of-change was 4.8 percent (1.048116) or 9.8 percent (1.098547) over 2 years.

Comment: Many commenters were concerned that they were unable to replicate the calculation of the charge inflation factor that CMS used in the proposed rule. One commenter requested that CMS add the claims data used to compute the charge inflation factor to the list of limited data set (LDS) files that can be ordered through the usual LDS data request process. Another commenter who was also focusing on replicating the charge inflation factor stated that it was unable to match the figures in the table from the proposed rule with publicly available data sources. The commenter further stated

that CMS has not made the necessary data available, or any guidance that describes whether and how it edited such data to arrive at the total of quarterly charges and charges per case it used to measure charge inflation. Consequently, the commenter stated that the table provided in the proposed rule is not useful in assessing the accuracy of the charge inflation figure that CMS used in the proposed rule to calculate the outlier threshold. In the absence of such data and how it was edited by CMS to arrive at the totals used in its charge inflation calculation, the commenter asserted that CMS has violated a principal tenet of the Administrative Procedure Act by not providing adequate notice to allow for meaningful comment.

Response: As stated in last year's rule, we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. The commenters did not suggest that CMS use charge data from a different period to compute the charge inflation factor. If we computed the charge inflation factor using the latest data available to the public at the time of issuance of this final rule, we would need to compare charge data from FY 2013 (October 2012–September 2013) to FY 2014 (October 2013–September 2014), data which would be at least 10 months old compared to the charge data we currently use, which is 4 months old. Furthermore, we note that, with regard to CCRs (as summarized below), the commenters suggested that CMS use the most recent data available when it calculates the outlier threshold. We share the commenters' view. Therefore, we are continuing to use the most recent charge data available to us at the time of this final rule to compute the charge inflation factor.

With respect to commenters who expressed concern that they were unable to replicate the calculation of the charge inflation factor that CMS used in the proposed rule, the information we provided in the proposed rule was sufficient for meaningful comment on our proposal and balances the commenter's requests that we use the latest claims data to compute the charge inflation factor with the current limitations of the LDS file. We note that we responded to similar comments on the replication of the charge inflation factor in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50375) and refer readers to that final rule.

Nevertheless, in response to the request for additional information, we are taking two actions. For the quarterly charge data table, we grouped claims data by quarter in order that the public would be able to replicate the claims summary for the claims with discharge dates through September 30, 2014, that are available under the current LDS structure. In order to provide even more information in response to the commenters' request, we will make available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the link on the left titled ''FY 2016 IPPS Final Rule Home Page'' and then click the link ''FY 2016 Final Rule Data Files'') a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. The second action we will take is 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.

In response to the commenters who requested additional detail on our calculation, we note that section II.A.4. of this Addendum describes the inclusion and exclusion of claims and charges used in the outlier calculation and charge inflation calculation. As we have done in the past, in the FY 2016 IPPS/LTCH PPS proposed rule, we proposed to establish the FY 2016 outlier threshold using hospital CCRs from the December 2014 update to the Provider-Specific File (PSF)—the most recent available data at the time of the proposed rule. We also proposed that if more recent data became available, we would use that data to calculate the final FY 2016 outlier threshold. For FY 2016, we also proposed to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below).

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 did for FY 2014 and FY 2015, we proposed to adjust the CCRs from the December 2014 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2013 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2014 update of the PSF. We note that, in the proposed rule, we used total transfer-adjusted cases from FY 2014 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 December 2013 operating national average case-weighted CCR of 0.288792 and a December 2014 operating national average case-weighted CCR of 0.280581. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2013 operating national average case-weighted CCR from the December 2014 operating national average case-weighted CCR and then dividing the result by the December 2013 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.971568.

We used the same methodology proposed above to adjust the capital CCRs. Specifically, for the proposed rule we calculated a December 2013 capital national average case-weighted CCR of 0.025014 and a December 2014 capital national average case-weighted CCR of 0.024500. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2013 capital national average case-weighted CCR from the December 2014 capital national average case-weighted CCR and then dividing the result by the December 2013 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.979474.

Consistent with our methodology used in the past and as stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe that it is appropriate to apply only a 1-year adjustment factor to the CCRs. On average, it takes approximately 9 months for a MAC to tentatively settle a cost report from the fiscal year end of a hospital's cost reporting period. The average ''age'' of hospitals' CCRs from the time the fiscal intermediary or the MAC inserts the CCR in the PSF until the beginning of FY 2016 is approximately 1 year. Therefore, as stated above, we believe a 1-year adjustment factor to the CCRs is appropriate.

As stated above, for FY 2016, we applied the FY 2016 payment rates and

policies from the proposed rule using cases from the FY 2014 MedPAR files in calculating the outlier threshold.

As discussed above, for FY 2016, we are applying the second year of the 3-year transitional wage index because of the adoption of the new OMB labor market area delineations. Also, as discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.H.3. of the preamble of this final 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 are calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State receives a wage index less than 1.0000 due to the rural and imputed 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 2016, it was necessary to apply the 3-year transitional wage indexes and adjust the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2016. If we did not take the above into account, our estimate of total FY 2016 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 2016 outlier payments, we proposed not to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We stated that 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 proposed not to make any assumptions regarding the effects of reconciliation on the outlier threshold calculation.

Comment: Commenters were concerned with CMS' decision not to consider outlier reconciliation in developing the outlier threshold and stated that it has not provided objective data concerning the number of hospitals that have been subjected to reconciliation and the amounts recovered during this process. The commenters' views were similar to comments received and responded to in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50376 through 50377).

Another commenter submitted the same comment as last year and cited CMS' response from the FY 2015 IPPS/LTCH PPS final rule (79 FR 50377). The commenter questioned CMS' response with the following comments: The commenter asked what is the basis for CMS' claim ''that the CCRs will reflect low costs and high charges that the commenter referred to, and when applied to the charges on the claim will result in less outlier payments for such cases because the costs of the case will be lower when compared to the total MS–DRG payments excluding outlier payments.'' The commenter cited the 2013 OIG Report and stated that the report seems to state the opposite of CMS' position when it states that ''high-outlier hospitals charged Medicare substantially more for the same MS–DRGs, yet had similar average lengths of stay and CCRs.'' The commenter further cited the same 2013 OIG report which stated ''that high-outlier hospitals had similar average CCRs, compared to all other hospitals, which means that the higher charges by the hospitals directly resulted in larger and more frequent outlier payments. As mentioned, Medicare applies a hospital's CCR to the covered charges on a claim to determine the estimated cost of services covered by the claim. The amount of the estimated cost determines whether Medicare makes an outlier payment and the amount received. In 2008, the average CCR at high-outlier hospitals was the same as the average CCR for all other hospitals, 0.35. CCRs declined, on average, during 2008–2011, to 0.30 at high-outlier hospitals and to 0.33 at all other hospitals. Although the high-outlier hospitals had higher charges, their CCR (that is, 0.30) was not significantly lower than the CCR of all other hospitals (that is, 0.33). Therefore, the higher charges led Medicare to calculate higher estimated costs for the high-outlier hospitals, and paying larger, more frequent outlier payments.''

The commenter concluded that it is neither consistent with the outlier statute nor reasonable for CMS, in modeling outlier payments for the upcoming fiscal year, to include outlier payments that were based on excessively high charges for particular MS–DRGs and not based on truly unusually high costs. The commenter suggested that, if CMS claims that such payments will not be recouped because they do not trigger reconciliation under current criteria, CMS explain how it plans to address the matter in setting the outlier fixed-loss cost threshold. The commenter suggested the following possibilities: Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual authorizes CMS to ''direct Medicare contractors to use an alternative CCR if CMS believes this will result in a more accurate CCR'' or a Medicare contractor ''may specify an alternative CCR if it believes that the CCR being applied is inaccurate.''

Response: We responded to similar comments in the FY 2015 IPPS/LTCH final rule (79 FR 50376 through 50377) and refer readers to that final rule. With regard to the OIG report that the commenter believed contradicted our statement in last year's final rule, we note that the OIG report used CCRs from 2008–2011. The CCRs are updated in the PSF at the time the MAC tentatively settles the hospital cost report, which is approximately 6 to 7 months after the cost report has been submitted. Thus, there is a lag in CCRs with the possibility that a CCR may be 18 months old from the time the cost report is submitted by the provider to the MAC until it is updated at the following tentative settlement. Because hospitals typically increase their charges, over time CCRs will decrease but, due to the lag these lower CCRs will not be reflected in the PSF until the following tentative settlement. Thus, it is possible that the PSF will reflect CCRs that are similar for hospitals with high and low outlier payments. In addition, providers determine what they will charge for items, services, and procedures provided to patients, and these charges are the amount that the providers bill for an item, service, or procedure. Moreover, different hospitals can have similar lengths of stay but different

CCRs. We encourage transparency with respect to hospital charges and have posted hospital charge data on the CMS Web site at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data*. In addition, as the commenter noted, there are mechanisms to avoid outlier overpayments or underpayments as CMS and the MACs have the authority to specify an alternative CCR. Also, in addition to the examples cited by the commenter, as we note in every proposed and final rule, hospitals can also request alternative CCRs. Therefore, if hospitals make these requests, these CCRs would be reflected in the PSF which would be used to compute the fixed-loss threshold.

As described in sections IV.H. and IV.I., respectively, of the preamble of this final 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 hospital VBP payment adjustments and the hospital readmissions payment adjustments in the outlier threshold calculation or the 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 will 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 proposed to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.

We noted that, to the extent section 1886(r) of the Act modifies the existing DSH payment methodology under section 1886(d)(5)(F) of the Act, the new 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 did for FY 2014 and FY 2015, for FY 2016, we proposed 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 stated that 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 stated that 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 in FY 2014 and FY 2015 to calculate the outlier fixed-loss cost threshold, for FY 2016, we proposed to include estimated FY 2016 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we proposed 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 outlier fixed-loss cost threshold methodology.

Using this methodology, we proposed an outlier fixed-loss cost threshold for FY 2016 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 $24,485.

In the proposed rule, we noted that the proposed FY 2016 fixed-loss cost threshold is lower than the FY 2015 final outlier fixed-loss cost threshold of $24,626. We stated that we believe that the decrease in the charge inflation factor (compared to the FY 2015 charge inflation factor) contributed to a lower outlier fixed-loss threshold for FY 2016. As charges decrease, so does the amount of outlier payments. As a result, it was necessary for us to lower the proposed outlier fixed-loss cost threshold to increase the amount of outlier payments expended in order to reach the 5.1 percent target.

Comment: One commenter believed that it is important that CMS accurately calculate prior year actual payment comparisons to the 5.1 percent target. The commenter asserted that it is not possible for CMS to appropriately modify its methodology to achieve an accurate result if it is not aware of, or misinformed about, inaccuracies resulting from prior the prior year methodology. The commenter cited the FY 2014 IPPS/LTCH PPS proposed rule as an example where CMS indicated that using partial year data for FY 2013 demonstrated that outlier payments would equal about 5.17 percent of overall payments, while in the FY 2015 IPPS/LTCH PPS final rule, CMS indicated that, for FY 2013, outlier payments would equal about 4.81 percent of MS–DRG payments. The commenter stated that this demonstrates that CMS' early estimate for FY 2013 was too high, as has often been the case. The commenter also cited the FY 2015 IPPS/LTCH PPS final rule correction notice (79 FR 59681) as another example where using the FY 2013 MedPAR file, CMS estimated actual FY 2014 outlier payments would be approximately 5.68 percent of actual total MS–DRG payments, while the current estimate, using available FY 2014 claims data, is that actual outlier payments for FY 2014 were approximately 5.34 percent of actual total MS–DRG payments.

The commenter stated that it was concerned that CMS believed it was over shooting its target amount for FY 2014 by 0.58 percent and this motivated CMS to dramatically increase the threshold for FY 2015, only to learn this year that its estimate was grossly overstated. The commenter concluded that it is critical that CMS not allow the use of incomplete data from prior years to affect its calculation of current period thresholds.

Another commenter noted that the final outlier threshold established by CMS is always significantly lower than the threshold set forth in the proposed rule. The commenter believed the decline is most likely due to the use of updated CCRs or other data in calculating the final threshold. The commenter stated that this emphasizes that CMS must use the most recent data available when it calculates the outlier threshold. The commenter cited as an example that, in the proposed rule, CMS used data from the December 2014 PSF file, but at the time the proposed rule was issued, the March 2015 PSF file was available.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50378 through 50379) and refer the reader to that rule for our response.

Comment: One commenter stated CMS' explanation of why the threshold decreased from FY 2015 to FY 2016 conflicts with its historical adjustments

to the outlier fixed-loss cost threshold. The commenter noted that, from FY 2013 to FY 2014, CMS decreased the outlier fixed-loss cost threshold even though the charge inflation factor increased compared to the previous year. Moreover, the commenter stated that CMS is incorrect that its model assumes that charges will decrease in FY 2016 when compared to FY 2015 for several reasons. First, the average charge per case from the FY 2014 MedPAR file (used to calculate the FY 2016 outlier fixed-loss cost threshold) is approximately 5 percent higher than the average charge per case from the FY 2013 MedPAR file (used to calculate the FY 2015 outlier fixed-loss cost threshold; 79 FR 50375 and 50379). Second, the proposed rule establishes a 1-year charge inflation factor of 4.8116 percent, which is only 0.2801 percent lower than the FY 2015 1-year charge inflation factor of 5.0917 percent (80 FR 24632 and 79 FR 50379). Accordingly, the commenter stated that the proposed rule is proposing to lower the outlier fixed-loss cost threshold even though charges are projected to increase (that is, net charge inflation) in FY 2016 (when compared to FY 2015). The commenter requested that CMS explain this reduction because the proposed reduction in the outlier fixed-loss cost threshold cannot be attributed to a decrease in charges (because charges increased).

Response: In our description comparing the proposed FY 2016 outlier threshold to the FY 2015 final threshold, we stated that the decrease in charges contributed to a lower threshold. We did not state that this was the only reason. When we conduct our modeling to determine the outlier threshold, we factor in all payments and policies that would affect actual payments for the upcoming fiscal year in order to estimate that outlier payments are 5.1 percent of total MS–DRG payments. As a result, there are many components of the payment system that can contribute to the increase and decrease of outlier payments. Also, we believe the commenter, by only comparing the 1-year change, is inadvertently distorting the variance of the charge inflation factor. For FY 2016, we are using claims from FY 2014, which requires a 2-year inflation factor. The actual variance in the charge inflation factor from FY 2015 to FY 2016 is 0.5880 percent (FY 2015 IPPS/LTCH PPS final rule 2-year inflation factor of 1.104427 minus FY 2016 IPPS/LTCH PPS proposed rule 2-year inflation factor 1.098547).

Comment: One commenter believed that the outlier threshold should be further reduced because outlier payments this year are on target to fall below the 5.1 percent target. The commenter suggested that CMS consider calculating the threshold with a target of 5.5 percent of inpatient spending in order to ensure that the final total of outlier payment is between the statutory requirements of 5 to 6 percent of total payments.

Another commenter recommended that that threshold be maintained at the FY 2014 level of $21,748 until CMS develops a more reliable methodology for meeting the 5.1 percent target. One other commenter also noted that CMS' estimate of FY 2015 outlier payments in the proposed rule was 4.88 percent, which is below the 5.1 percent target. The commenter believed that the proposed FY 2016 threshold was understated. As a result, the commenter suggested that CMS apply the following formula to compute the FY 2016 outlier threshold: Step 1—FY 2015 Difference = (5.1 percent Target − 4.88 percent estimate from FY 2015 = 0.22 percent)/ 4.88 percent estimate from FY 2015 = 4.51 percent; Step 2—Suggested FY 2016 Threshold = Threshold from FY 2015 of $24,626 * (100 − 4.51 from Step 1 = 95.49 percent) = $23,515.

Response: As we responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (78 FR 50379), section 1886(d)(5)(A)(iv) of the Act requires outlier payments to be not less than 5 percent nor more than 6 percent of total estimated or projected payments in that year. Therefore, we cannot adopt the commenters' suggestions of using a target of 5.5 percent, maintaining the threshold at the FY 2014 level, or using a forecast correction to compute the outlier threshold. When we calculate the threshold, we use the latest data that are available at the time of the development of the proposed and final rules in order to estimate that outlier payments are 5.1 percent of total payments.

Comment: One commenter was concerned that CMS constantly misses the 5.1 percent target. The commenter recommended that CMS conduct additional analysis to evaluate the methodology for incorporating uncompensated care and DSH payment into the outlier threshold calculation.

Response: As discussed above, we include uncompensated care payments in our calculation of the fixed-loss outlier threshold. Without additional information or data analysis, we are unsure what exactly the commenter is referencing when the commenter stated that CMS should further evaluate the methodology for incorporating uncompensated care and DSH payments into the outlier threshold calculation.

After consideration of the public comments we received, we are not making any changes to our methodology in this final rule for FY 2016. Therefore, we are using the same methodology we proposed to calculate the final outlier threshold.

As described above, we used the latest claims data from the MedPAR file to compute the charge inflation factor. Similar to the table provided in the proposed rule, for this final rule, we are providing the following table that displays covered charges and cases by quarter in the periods used to calculate the charge inflation factor.

Quarter	Covered charges (April 1, 2013, through March 31, 2014)	Cases (April 1, 2013, through March 31, 2014)	Covered charges (April 1, 2014, through March 31, 2015)	Cases (April 1, 2014, through March 31, 2015)
1	$126,565,555,412	2,486,502	$100,567,278,074	1,932,720
2	118,792,100,497	2,505,875	121,989,001,463	2,444,426
3	115,796,137,233	2,424,262	118,516,052,865	2,351,444
4	119,439,461,865	2,405,925	122,175,830,268	2,396,231
Total	480,593,255,007	9,822,564	463,248,162,670	9,124,821

Under our current methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2016, based on the data from the table above, we compared the average covered charge per case of $48,927 ($480,593,255,007/9,822,564) from the third quarter of FY 2013 through the second quarter of FY 2014 (April 1, 2013, through March 31, 2014) to the average covered charge per case of $50,768 ($463,248,162,670/9,124,821)

from the third quarter of FY 2014 through the second quarter of FY 2015 (April 1, 2014, through March 31, 2015). This rate-of-change is 3.7 percent (1.037616) or 7.7 percent (1.076647) over 2 years.

As we have done in the past, we are establishing the FY 2016 outlier threshold using hospital CCRs from the March 2015 update to the Provider-Specific File (PSF)—the most recent available data at the time of development of this final rule. For FY 2016, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). 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 did for FY 2014 and for FY 2015, we are adjusting the CCRs from the March 2015 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2014 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2015 update of the PSF. We note that we used total transfer-adjusted cases from FY 2014 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 as 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 methodology above, we calculated a March 2014 operating national average case-weighted CCR of 0.287139 and a March 2015 operating national average case-weighted CCR of 0.278565. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2014 operating national average case-weighted CCR from the March 2015 operating national average case-weighted CCR and then dividing the result by the March 2014 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.970141.

We also used the same methodology above to adjust the capital CCRs. Specifically, we calculated a March 2014 capital national average case-weighted CCR of 0.024879 and a March 2015 capital national average case-weighted CCR of 0.024243. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the March 2014 capital national average case-weighted CCR from the March 2015 capital national average case-weighted CCR and then dividing the result by the March 2014 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.974442.

Consistent with our methodology in the past and as stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe that it is appropriate to apply only a 1-year adjustment factor to the CCRs. On average, it takes approximately 9 months for a MAC to tentatively settle a cost report from the fiscal year end of a hospital's cost reporting period. The average ''age'' of hospitals' CCRs from the time the fiscal intermediary or the MAC inserts the CCR in the PSF until the beginning of FY 2016 is approximately 1 year. Therefore, as stated above, we believe a 1-year adjustment factor to the CCRs is appropriate.

As stated above, for FY 2016, we applied the FY 2016 payment rates and policies using cases from the FY 2014 MedPAR files in calculating the outlier threshold.

As discussed above, for FY 2016, we are applying the second year of the 3-year transitional wage index because of the adoption of the new OMB labor market area delineations. Also, as discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.H.3. of the preamble of this final 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 are calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State receives a wage index less than 1.0000 due to the rural and imputed 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 outlier threshold for FY 2016, it was necessary to apply the 3-year transitional wage indexes and adjust the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2016. If we did not take the above into account, our estimate of total FY 2016 payments would be too low, and, as a result, our 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), as we proposed and for the reasons discussed above, in our projection of FY 2016 outlier payments, we are not making any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement.

As described in sections IV.E. and IV.F. respectively, of the preamble of this final 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 hospital VBP payment adjustments and the hospital readmissions payment adjustments in the outlier threshold calculation or the 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 will 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 excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the 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 new 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 did for

FYs 2014 and 2015, we also for FY 2016 allocated 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 best approximates the amount we will pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we will 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 in FYs 2014 and 2015 to calculate the outlier fixed-loss cost threshold, for FY 2016, we included estimated FY 2016 uncompensated care payments in the computation of the outlier fixed-loss cost threshold. Specifically, we used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we calculated a final outlier fixed-loss cost threshold for FY 2016 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payments, and any add-on payments for new technology, plus $22,544.

(2) Other 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 2016 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 6.35 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we reduced the FY 2016 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that were applied to the standardized amount based on the FY 2016 outlier threshold are as follows:

	Operating standardized amounts	Capital Federal rate
National	0.949000	0.936519
Puerto Rico	0.935042	0.919230

We applied the outlier adjustment factors to the FY 2016 payment rates after removing the effects of the FY 2015 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we 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 1.21 or capital CCRs greater than 0.175, 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 Web site) contains the 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. Effective for discharges occurring on or after October 1, 2015, these statewide average ratios will replace the ratios posted on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Tables.html*. Table 8B listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the comparable statewide average capital CCRs. As previously stated, the CCRs in Tables 8A and 8B will be used during FY 2016 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 Web site) contains the 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 ratio at any time as long as the guidelines of Change Request 3966 are followed. In addition, 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 Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf*.

(3) FY 2014 and FY 2015 Outlier Payments

In the FY 2015 IPPS/LTCH PPS final rule correction notice (79 FR 59681), we stated that, based on available data, we estimated that actual FY 2014 outlier payments would be approximately 5.68 percent of actual total MS–DRG payments. This estimate was computed based on simulations using the FY 2013 MedPAR file (discharge data for FY 2013 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2014 claims, but instead reflected the application of FY 2014 payment rates and policies to available FY 2013 claims.

Our current estimate, using available FY 2014 claims data, is that actual outlier payments for FY 2014 were approximately 5.38 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2014, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2014. 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 2014 are equal to 5.1 percent of total MS–DRG payments.

We currently estimate that, using the latest CCRs from the March 2015 update of the PSF, actual outlier payments for FY 2015 will be approximately 4.65 percent of actual total MS–DRG payments, approximately 0.45 percentage point lower than the 5.1 percent we projected when setting the outlier policies for FY 2015. This estimate of 4.65 percent is based on simulations using the FY 2014 MedPAR file (discharge data for FY 2014 claims).

Comment: One commenter requested that CMS clarify its methodology used to calculate historical outlier payments. The commenter noted that CMS used FY 2014 claims data to model the total estimated actual outlier payments for FY 2014. The commenter stated that commenters have repeatedly noted that CMS' model overestimates the amount of total outlier payments, as compared to using actual claims data. The commenter further stated that in the FYs 2013 and 2014 IPPS/LTCH PPS final rules (77 FR 53698 and 78 FR 50983, respectively), one commenter used cost report data from the HCRIS to analyze the historical actual outlier payout from 2003 through 2010 and 2012 through 2014, which demonstrated that total outlier payments as a percentage of total MS–DRG payments are substantially lower than what CMS has ''modeled.''

The commenter stated that actual outlier payment estimates should be objectively calculated independent of HHS's ''modeling'' methodology. The commenter further stated that, in setting the fixed-loss cost threshold, CMS considers prior fiscal years' outlier payments and therefore it is important to have an accurate tally of those payments. The commenter concluded that CMS' estimates are unreliable and commenters have demonstrated far more reliable methods.

Response: As stated above, we do not rely upon historical actual outlier payments to determine the fixed-loss cost threshold. When we calculate the threshold, we use the latest data that are available at the time of the proposed and final rule in order to estimate that outlier payments are 5.1 percent of total payments. With regard to the remainder of the commenter's views, we have responded to similar comments in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51796) and refer readers to that final rule.

Comment: One commenter asked if CMS can confirm if calculations of historical actual outlier payments based on HCRIS data produce lower total outlier payments than CMS' methodology. The commenter stated that the correct calculation of actual outlier payments is important because CMS relies upon historical actual outlier payments to determine the fixed-loss cost threshold and general IPPS payments. The commenter noted that, in the proposed rule (80 FR 24665), CMS stated that ''The impact of moving from our estimate of FY 2015 outlier payments, 4.9 percent, to the proposed estimate of FY 2016 outlier payments, 5.1 percent, would result in an increase of 0.2 percent in FY 2016 payments relative to FY 2015.'' Based on this statement, the commenter stated that if the estimate of FY 2015 outlier payments was lower than 4.9 percent, CMS would need to make a corresponding upward adjustment in FY 2016 payments relative to FY 2015. The commenter further stated that if CMS' modeling efforts to calculate historical outlier payments have consistently underestimated actual outlier payments, CMS should adjust FY 2016 payments to compensate for the miscalculation of historical outlier payments. The commenter believed that such a correction would not be retroactive per se as CMS would simply be making the adjustment for upcoming fiscal year payments.

Response: Contrary to the commenter's statement, as stated above, we do not rely upon historical actual outlier payments to determine the fixed-loss cost threshold. When we calculate the threshold, we use the latest data that are available at the time of the proposed and final rule in order to estimate that outlier payments are 5.1 percent of total payments. For purposes of impacts and assessing whether or not potential changes to the outlier methodology may be warranted, we estimate outlier payments from the preceding fiscal year. However, this estimate does not impact the calculation of the fixed-loss threshold for the upcoming fiscal year. With regard to using HCRIS data to measure actual outlier payments, hospitals' cost reporting periods do not match the period of the Federal fiscal year. For example, many hospitals submit cost reports based on a calendar year (January 1 through December 31), while the Federal fiscal year runs from October 1 through September 30. Outlier payments are reported in the aggregate on the cost report, and it is currently not possible to break out outlier payments from the cost report to a Federal fiscal year if the cost report submitted by the provider is using a different reporting period.

5. FY 2016 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 Web site) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2016. The Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 69.6 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 applying a labor-related share of 62 percent, unless application of that percentage will 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 standardized amounts reflecting the applicable percentage increases for FY 2016.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of the Puerto Rico payment rate is based on the

discharge-weighted average of the national large urban standardized amount (this amount is set forth in Table 1A). The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2016 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). This table also includes the Puerto Rico-specific standardized amounts. The labor-related share applied to the Puerto Rico-specific standardized amount is the labor-related share of 63.2 percent, or 62 percent, depending on which provides higher payments to the hospital. (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 2015 national standardized amount to the FY 2016 national standardized amount. The second through fifth columns display the changes from the FY 2015 standardized amounts for each applicable FY 2016 standardized amount. The first row of the table shows the updated (through FY 2015) average standardized amount after restoring the FY 2015 offsets for outlier payments, demonstration budget neutrality, geographic reclassification budget neutrality, new labor market delineation wage Index transition budget neutrality and the retrospective documentation and coding adjustment under section 7(b)(1)(B) of Public Law 110–90. The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2015 adjustment factors are not removed from this table.

COMPARISON OF FY 2015 STANDARDIZED AMOUNTS TO THE FY 2016 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 2015 Base Rate after removing: 1. FY 2015 Geographic Reclassification Budget Neutrality (0.990429). 2. FY 2015 Rural Community Hospital Demonstration Program Budget Neutrality (0.999313). 3. Cumulative FY 2008, FY 2009, FY 2012, FY 2013 and FY 2014, FY 2015 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012 (0.9329) 4. FY 2015 Operating Outlier Offset (0.948999) 5. FY 2015 New Labor Market Delineation Wage Index Transition Budget Neutrality Factor (0.998854)	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,324.23 Nonlabor (30.4%): $1,888.74. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,852.04 Nonlabor (38%): $2,360.93.	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,324.23 Nonlabor (30.4%): $1,888.74. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,852.04 Nonlabor (38%): $2,360.93.	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,324.23 Nonlabor (30.4%): $1,888.74. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,852.04 Nonlabor (38%): $2,360.93.	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,324.23 Nonlabor (30.4%): $1,888.74. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,852.04 Nonlabor (38%): $2,360.93.
FY 2016 Update Factor	1.017	1.005	1.011	0.999.
FY 2016 MS-DRG Recalibration and Wage Index Budget Neutrality Factor.	0.997150	0.997150	0.997150	0.997150.
FY 2016 Reclassification Budget Neutrality Factor.	0.987905	0.987905	0.987905	0.987905.
FY 2016 Rural Community Demonstration Program Budget Neutrality Factor.	0.999861	0.999861	0.999861	0.999861.
FY 2016 Operating Outlier Factor	0.949000	0.949000	0.949000	0.949000.
Cumulative Factor: FY 2008, FY 2009, FY 2012, FY 2013, FY 2014, FY 2015 and FY 2016 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012.	0.9255	0.9255	0.9255	0.9255.
FY 2016 New Labor Market Delineation Wage Index 3-Year Hold Harmless Transition Budget Neutrality Factor.	0.999996	0.999996	0.999996	0.999996.
National Standardized Amount for FY 2016 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (69.6/30.4).	Labor: $3,804.40 Nonlabor: $1,661.69	Labor: $3,759.51 Nonlabor: $1,642.08	Labor: $3,781.96 Nonlabor: $1,651.89	Labor: $3,737.07. Nonlabor: $1,632.28.

COMPARISON OF FY 2015 STANDARDIZED AMOUNTS TO THE FY 2016 STANDARDIZED AMOUNTS—Continued

	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
National Standardized Amount for FY 2016 if Wage Index is less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38).	Labor: $3,388.98 ..... Nonlabor: $2,077.11 ..	Labor: $3,348.99 ..... Nonlabor: $2,052.60 ..	Labor: $3,368.99 ..... Nonlabor: $2,064.86 ..	Labor: $3,329.00 Nonlabor: $2,040.35.

The following table illustrates the changes from the FY 2015 Puerto Rico-specific payment rate for hospitals located in Puerto Rico. The second column shows the changes from the FY 2015 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index greater than 1.0000. The third column shows the changes from the FY 2015 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index less than or equal to 1.0000. The first row of the table shows the updated (through FY 2015) Puerto Rico-specific payment rate after restoring the FY 2015 offsets for Puerto Rico-specific outlier payments, rural community hospital demonstration program budget neutrality, and the geographic reclassification budget neutrality. The MS–DRG recalibration budget neutrality adjustment factor is cumulative and is not removed from this table.

COMPARISON OF FY 2015 PUERTO RICO-SPECIFIC PAYMENT RATE TO THE FY 2016 PUERTO RICO-SPECIFIC PAYMENT RATE

	Update (1.7 percent); wage index is greater than 1.0000; labor/non-labor share percentage (63.2/36.8)	Update (1.7 percent); wage index is less than or equal to 1.0000; labor/non-labor share percentage (62/38)
FY 2015 Puerto Rico Base Rate, after removing: 1. FY 2015 Geographic Reclassification Budget Neutrality (0.990429). 2. FY 2015 Rural Community Hospital Demonstration Program Budget Neutrality (0.999313). 3. FY 2015 Puerto Rico Operating Outlier Offset (0.926334). 4. FY 2015 New Labor Market Delineation Wage Index Transition Budget Neutrality Factor (0.998854).	Labor: $1,758.02 ..... Nonlabor: $1,023.66 ..	Labor: $1,724.64. Nonlabor: $1,057.04.
FY 2016 Update Factor	1.017	1.017.
FY 2016 MS-DRG Recalibration Budget Neutrality Factor	0.998399	0.998399.
FY 2016 Reclassification Budget Neutrality Factor	0.987905	0.987905.
FY 2016 Rural Community Hospital Demonstration Program Budget Neutrality Factor	0.999861	0.999861.
FY 2016 New Labor Market Delineation Wage Index 3-Year Hold Harmless Transition Budget Neutrality Factor.	0.999996	0.999996.
FY 2016 Puerto Rico Operating Outlier Factor	0.935042	0.935042.
Puerto Rico-Specific Payment Rate for FY 2016	Labor: $1,648.66 ..... Nonlabor: $959.98	Labor: $1,617.36. Nonlabor: $991.28.

B. 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 Web site), contain the labor-related and nonlabor-related shares that we used to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2016. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. 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 and Puerto Rico prospective payment rates, respectively, 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. In section III of the preamble of this final rule, we discuss the data and methodology for the FY 2016 wage index.

2. 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 such 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 located 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 2014, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), 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 continuing to use the same COLA factors in FY 2016 that were used in FY 2015 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. Below is a table listing the COLA factors for FY 2016.

FY 2016 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	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
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 will occur in FY 2018.

C. Calculation of the Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2016

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs and MDHs, for FY 2016 equals the Federal rate (which includes uncompensated care payments).

We note that 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).

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section IV.D. of the preamble of this final 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 2016 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2016 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.

The prospective payment rate for hospitals located in Puerto Rico for FY 2016 equals 25 percent of the Puerto Rico-specific payment rate plus 75 percent of the applicable national rate.

1. Federal Rate

The Federal rate is determined as follows:

Step 1—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 2—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3—For hospitals located in Alaska and Hawaii, multiply the nonlabor-related portion of the standardized amount by the applicable cost-of-living adjustment factor.

Step 4—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if applicable, under Step 3).

Step 5—Multiply the final amount from Step 4 by the relative weight corresponding to the applicable MS–DRG (Table 5 listed in section VI. of this Addendum and available via the Internet on the CMS Web site).

The Federal payment rate as determined in Step 5 may then be further adjusted if the hospital qualifies for either the IME or DSH adjustment. In addition, 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 payment in Step 5 would be increased by a specified formula. 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. Finally, we add the uncompensated care payment to the total claim payment amount. We note that, as discussed above, we take uncompensated care 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 (which, as discussed in section IV.D. of the preamble of this final 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.

As noted above, 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). As discussed previously, currently MDHs are 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 greater of the updated hospital-specific rates based on either FY 1982, FY 1987 or FY 2002 costs per discharge.

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). We also refer readers to section IV.D. of the preamble of this final rule for a complete discussion on empirically justified Medicare DSH and uncompensated care payments.

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2016

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 applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2016	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
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.6	−0.6
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−1.2	0.0	−1.2
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Applicable Percentage Increase Applied to Hospital−specific rate	1.7	0.5	1.1	−0.1

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.A. of the preamble of this final 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, a SCH's and MDH's hospital-specific rate is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.998399, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate that an SCH and an MDH will receive for its discharges beginning on or after October 1, 2015. We note that, in this final rule, for FY 2016, 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 final rule for a complete discussion regarding our finalized 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.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or After October 1, 2015, and Before October 1, 2016

Section 1886(d)(9)(E)(iv) of the Act provides that, effective for discharges occurring on or after October 1, 2004, hospitals located in Puerto Rico are paid based on a blend of 75 percent of the national prospective payment rate and 25 percent of the Puerto Rico-specific rate.

a. Puerto Rico-Specific Rate

The Puerto Rico-specific prospective payment rate is determined as follows:

Step 1—Select the applicable average standardized amount considering the applicable wage index (obtained from Table 1C published in section VI. of this Addendum and available via the Internet on the CMS Web site).

Step 2—Multiply the labor-related portion of the standardized amount by the applicable Puerto Rico-specific wage index.

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount.

Step 4—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (obtained from Table 5 listed in section VI. of this Addendum and available via the Internet on the CMS Web site).

Step 5—Multiply the result in Step 4 by 25 percent.

b. National Prospective Payment Rate

The national prospective payment rate is determined as follows:

Step 1—Select the applicable national average standardized amount.

Step 2—Multiply the labor-related portion of the national average

standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the national average standardized amount.

Step 4—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (obtained from Table 5 listed in section VI. of this Addendum and available via the Internet on the CMS Web site).

Step 5—Multiply the result in Step 4 by 75 percent.

The sum of the Puerto Rico-specific rate and the national prospective payment rate computed above equals the prospective payment rate for a given discharge for a hospital located in Puerto Rico. This payment rate is then further adjusted if the hospital qualifies for either the IME or DSH adjustment.

Finally, we add the uncompensated care payment to the total claim payment amount. We note that, as discussed above, we take uncompensated care payments into consideration when calculating outlier payments.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2016

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period, over a 10-year transition period (which extended through FY 2001) the payment methodology for Medicare acute care hospital inpatient capital-related costs changed from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

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 capital Federal rate for FY 2016, which is effective for discharges occurring on or after October 1, 2015.

The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. For FY 1992, we computed the standard Federal payment rate for capital-related costs under the IPPS by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the capital standard Federal rate, as provided at § 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 blended payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. In accordance with section 1886(d)(9)(A) of the Act, under the IPPS for acute care hospital operating costs, hospitals located in Puerto Rico are paid for operating costs under a special payment formula. Effective October 1, 2004, in accordance with section 504 of Public Law 108–173, the methodology for operating payments made to hospitals located in Puerto Rico under the IPPS was revised to make payments based on a blend of 25 percent of the applicable standardized amount specific to Puerto Rico hospitals and 75 percent of the applicable national average standardized amount. In conjunction with this change to the operating blend percentage, effective with discharges occurring on or after October 1, 2004, we also revised the methodology for computing capital payments made to hospitals located in Puerto Rico to be based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the national capital Federal rate (69 FR 49185).

A. Determination of the Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2016. In particular, we explain why the FY 2016 capital Federal rate increases approximately 0.85 percent, compared to the FY 2015 capital Federal rate. As discussed in the impact analysis in Appendix A to this final rule, we estimate that capital payments per discharge will increase approximately 2.3 percent during that same period. Because capital payments constitute about 10 percent of hospital payments, a percent change in the capital Federal rate yields only about 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-increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2016 under that framework is 1.3 percent based on the best data available at this time. The update factor under that framework is based on a projected 1.3 percent increase in the FY 2010-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of 0.0 percentage point. As discussed below 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 2016 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are applying in the update framework for FY 2016.

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 patients 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 2016, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will equal 0.5 percent for FY 2016. 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, as we proposed, the net adjustment for case-mix change in FY 2016 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 2014 DRG reclassification and recalibration as part of our update for FY 2016. We estimate that FY 2014 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, as we proposed, we are making a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2016.

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 2014 update, for which there is historical data. That is, current historical data indicate that the forecasted FY 2014 CIPI (1.2 percent) used in calculating the FY 2014 update factor was equal to the actual realized price increases (also 1.2 percent). Therefore, as we proposed, we are not making an adjustment for a forecast error in the update for FY 2016.

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 increases 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 increase 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 final rule, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2016 (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 2016, we are using an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2009 and extending through FY 2013. Based on these data, we estimated that case-mix constant intensity declined during FYs 2009 through 2013. 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 declined during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2016. Therefore, as we proposed, we are making a 0.0 percentage point adjustment for intensity in the update for FY 2016.

Above, we described the basis of the components used to develop the 1.3 percent capital update factor under the capital update framework for FY 2016 as shown in the table below.

CMS FY 2016 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.3
Intensity	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Subtotal	1.3
Effect of FY 2014 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.3

*The capital input price index is based on the FY 2010-based CIPI.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2015 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS

payments for FY 2016. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2015, Chapter 3, available on the Web site at: *http://www.medpac.gov*.)

2. 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 2015, we estimated that outlier payments for capital would equal 6.18 percent of inpatient capital-related payments based on the capital Federal rate in FY 2015. Based on the thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 6.35 percent for inpatient capital-related payments based on the capital Federal rate in FY 2016. Therefore, we are applying an outlier adjustment factor of 0.9365 in determining the capital Federal rate for FY 2016. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2016 will be higher than the percentage for FY 2015.

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 FY 2016 outlier adjustment of 0.9365 is a − 0.18 percent change from the FY 2015 outlier adjustment of 0.9382. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2016 is 0.9982 (0.9365/0.9382). Thus, the outlier adjustment will decrease the FY 2016 capital Federal rate by 0.18 percent compared to the FY 2015 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. Because we implemented a separate GAF for Puerto Rico, we apply separate budget neutrality adjustments for the national GAF and the Puerto Rico GAF. We apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. Separate adjustments were unnecessary for FY 1998 and earlier because the GAF for Puerto Rico was implemented in FY 1998.

To determine the factors for FY 2016, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2015 MS–DRG classifications and relative weights and the FY 2015 GAF to estimated aggregate capital Federal rate payments based on the FY 2015 MS–DRG classifications and relative weights and the FY 2016 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are applying an incremental budget neutrality adjustment factor of 0.9979 for FY 2016 to the previous cumulative FY 2015 adjustment factor of 0.9884, yielding an adjustment factor of 0.9864 through FY 2016. For the Puerto Rico GAFs, we are applying an incremental budget neutrality adjustment factor of 0.9993 for FY 2016 to the previous cumulative FY 2015 adjustment factor of 1.0082, yielding a cumulative adjustment factor of 1.0075 through FY 2016.

We then compared estimated aggregate capital Federal rate payments based on the FY 2015 MS–DRG relative weights and the FY 2016 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the FY 2016 MS–DRG classifications and relative weights and the FY 2016 GAFs. The incremental adjustment factor for DRG classifications and changes in relative weights is 0.9994 both nationally and for Puerto Rico. The cumulative adjustment factors for MS–DRG classifications and changes in relative weights and for changes in the GAFs through FY 2016 are 0.9858 nationally and 1.0069 for Puerto Rico. (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 (the national capital rate and the Puerto Rico capital rate are determined separately) 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 cumulative adjustment factor of 0.9973 (the product of the incremental national GAF budget neutrality adjustment factor of 0.9979 and the incremental DRG budget neutrality adjustment factor of 0.9994) accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs. It also incorporates the effects on the GAFs of FY 2016 geographic reclassification decisions made by the MGCRB compared to FY 2015 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Capital Federal Rate for FY 2016

For FY 2015, we established a capital Federal rate of $434.97 (79 FR 59684). We are establishing an update of 1.3 percent in determining the FY 2016 capital Federal rate for all hospitals. As a result of this update and the budget neutrality factors discussed above, we are establishing a national capital Federal rate of $438.65 for FY 2016. The national capital Federal rate for FY 2016 was calculated as follows:

- The FY 2016 update factor is 1.013, that is, the update is 1.3 percent.
- The FY 2016 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 0.9973.
- The FY 2016 outlier adjustment factor is 0.9365.

(We note that, as discussed in section VI.C. of the preamble of this final rule,

we are not making an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rates for FY 2016.)

Because the FY 2016 capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not making additional adjustments in the capital Federal rate for these factors, other than the budget neutrality factor for changes in the MS–DRG classifications and relative weights and for changes in the GAFs.

We are providing the following chart that shows how each of the factors and adjustments for FY 2016 affects the computation of the FY 2016 national capital Federal rate in comparison to the FY 2015 national capital Federal rate. The FY 2016 update factor has the effect of increasing the capital Federal rate by 1.3 percent compared to the FY 2015 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.27 percent. The FY 2016 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.18 percent compared to the FY 2015 capital Federal rate. The combined effect of all the changes will increase the national capital Federal rate by approximately 0.85 percent compared to the FY 2015 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2015 CAPITAL FEDERAL RATE AND FY 2016 CAPITAL FEDERAL RATE

	FY 2015	FY 2016	Change	Percent change
Update Factor [1]	1.0150	1.0130	1.0130	1.3
GAF/DRG Adjustment Factor [1]	0.9993	0.9973	0.9973	−0.27
Outlier Adjustment Factor [2]	0.9382	0.9365	0.9982	−0.18
Capital Federal Rate	$434.97	$438.65	1.0085	0.85

[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 2015 to FY 2016 resulting from the application of the 0.9973 GAF/DRG budget neutrality adjustment factor for FY 2016 is a net change of 0.9973 (or −0.27 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 FY 2016 outlier adjustment factor is 0.9365/0.9382, or 0.9982 (or −0.18 percent).

In this final rule, we also are providing the following chart that shows how the final FY 2016 capital Federal rate differs from the proposed FY 2016 capital Federal rate as presented in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24640).

COMPARISON OF FACTORS AND ADJUSTMENTS: PROPOSED FY 2016 CAPITAL FEDERAL RATE AND FINAL FY 2016 CAPITAL FEDERAL RATE

	Proposed FY 2016	Final FY 2016	Change	Percent change
Update Factor	1.0130	1.0130	1.0000	0.00
GAF/DRG Adjustment Factor	0.9976	0.9973	0.9997	−0.30
Outlier Adjustment Factor	0.9357	0.9365	1.0008	0.08
Capital Federal Rate	438.40	438.65	1.0006	0.06

5. Special Capital Rate for Puerto Rico Hospitals

Section 412.374 provides for the use of a blended payment system for payments made to hospitals located in Puerto Rico under the PPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. Under the broad authority of section 1886(g) of the Act, beginning with discharges occurring on or after October 1, 2004, capital payments made to hospitals located in Puerto Rico are based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate. The Puerto Rico capital rate is derived from the costs of Puerto Rico hospitals only, while the capital Federal rate is derived from the costs of all acute care hospitals participating in the IPPS (including Puerto Rico).

To adjust hospitals' capital payments for geographic variations in capital costs, we apply a GAF to both portions of the blended capital rate. The GAF is calculated using the operating IPPS wage index, and varies depending on the labor market area or rural area in which the hospital is located. We use the Puerto Rico wage index to determine the GAF for the Puerto Rico part of the capital-blended rate and the national wage index to determine the GAF for the national part of the blended capital rate.

Because we implemented a separate GAF for Puerto Rico in FY 1998, we also apply separate budget neutrality adjustment factors for the national GAF and for the Puerto Rico GAF. However, we apply the same budget neutrality adjustment factor for MS–DRG reclassifications and recalibration nationally and for Puerto Rico. The budget neutrality adjustment factors for the national GAF and for the Puerto Rico GAF and the budget neutrality factor for MS–DRG reclassifications and recalibration (which is the same nationally and for Puerto Rico) are discussed in section III.A.3. of this Addendum.

In computing the payment for a particular Puerto Rico hospital, the Puerto Rico portion of the capital rate (25 percent) is multiplied by the Puerto Rico-specific GAF for the labor market area in which the hospital is located, and the national portion of the capital rate (75 percent) is multiplied by the national GAF for the labor market area in which the hospital is located (which is computed from national data for all hospitals in the United States and Puerto Rico).

For FY 2015, the special capital rate for hospitals located in Puerto Rico was $209.45 (79 FR 59683). With the changes we are making to the factors used to determine the capital Federal rate, the FY 2016 special capital rate for hospitals in Puerto Rico is $212.56.

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2016

For purposes of calculating payments for each discharge during FY 2016, 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 outlier thresholds for FY 2016 are in section II.A. of this Addendum. For FY 2016, 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 fixed-loss amount of $22,544.

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. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50603 through 50607), we rebased and revised the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. For a complete discussion of this rebasing, we refer readers to the FY 2014 IPPS/LTCH PPS final rule.

2. Forecast of the CIPI for FY 2016

Based on the latest forecast by IHS Global Insight, Inc. (second quarter of 2015), we are forecasting the FY 2010-based CIPI to increase 1.3 percent in FY 2016. This reflects a projected 1.8 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.6 percent increase in other capital expense prices in FY 2016, partially offset by a projected 1.4 percent decline in vintage-weighted interest expense prices in FY 2016. The weighted average of these three factors produces the forecasted 1.3 percent increase for the FY 2010-based CIPI as a whole in FY 2016.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2016

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. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

As discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24641), the FY 2016 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, and RNHCIs is the estimated percentage increase in the IPPS operating market basket for FY 2016, in accordance with applicable regulations at § 413.40. Based on IHS Global Insight, Inc.'s 2015 first quarter forecast, we estimated that the FY 2010-based IPPS operating market basket update for FY 2016 would be 2.7 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed that if more recent data became available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2016. Therefore, based on IHS Global Insight, Inc.'s 2015 second quarter forecast, with historical data through the first quarter of 2015, we estimate that the FY 2010-based IPPS operating market basket update for FY 2016 is 2.4 percent (that is, the estimate of the market basket rate-of-increase). 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), and RNHCIs, the FY 2016 rate-of-increase percentage that will be applied to the FY 2015 target amounts in order to determine the final FY 2016 target amounts is 2.4 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 final rule and section V. of the Addendum to this final rule for the update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2016. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Updates to the Payment Rates for the LTCH PPS for FY 2016

A. LTCH PPS Standard Federal Payment Rate for FY 2016

1. Background

In section VII. of the preamble of this final rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2016.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we

updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Therefore, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket update as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also made an adjustment to account for the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal rate as set forth in the regulations at §§ 412.523(c)(3)(iv) through (c)(3)(vii). For FYs 2012, 2013, 2014, and 2015, we updated the standard Federal rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by section 1886(m)(3)(A) of the Act as set forth in the regulations at §§ 412.523(c)(3)(viii) through (c)(3)(ix).

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal 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 final rule.

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. (As noted in section VII.D.2.a. of the preamble of this final 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 FY 2015, consistent with our historical practice, we established an update to the LTCH PPS standard Federal rate based on the full estimated LTCH PPS market basket increase of 2.9 percent and the 0.7 percentage point reductions required by sections 1886(m)(3)(A)(i) and 1886(m)(3)(A)(ii) with 1886(m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xi) of the regulations, we established an annual update of 2.2 percent to the standard Federal rate for FY 2015 (79 FR 50391through 50392).

For FY 2016, as discussed in greater detail in section VII.D.2. of the preamble of this final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate based on the full estimated increase in the LTCH PPS market basket, less the MFP adjustment consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. In addition, as discussed in greater detail in section VII.D.2. of the preamble of this final rule, the annual update is further reduced by 2.0 percentage points for LTCHs that fail to submit quality reporting data in accordance with the requirements of the LTCH QRP under section 1886(m)(5) of the Act.

Specifically, in this final rule, consistent with our proposal and based on the best available data, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.7 percent, which is based on the full estimated increase in the LTCH PPS market basket of 2.4 percent, less the MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. For LTCHs that fail to submit the required quality reporting data for FY 2016 in accordance with the LTCH QRP, the annual update is further reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act (as discussed in greater detail in section VII.D.2.c. of the preamble of this final rule). Accordingly, we are establishing an annual update to the LTCH PPS standard Federal payment rate of -0.3 percent for LTCHs that fail to submit the required quality reporting data for FY 2016. This -0.3 percent update was calculated based on the full estimated increase in the LTCH PPS market basket of 2.4 percent, less a MFP adjustment of 0.5 percentage point, less an additional adjustment of 0.2 percentage point required by the statute, and less 2.0 percentage points for failure to submit quality reporting data as required by section 1886(m)(5) of the Act.

2. Development of the FY 2016 LTCH PPS Standard Federal Payment Rate

We continue to believe that the annual update to the LTCH PPS standard Federal payment rate should be based on the most recent estimate of the increase in the LTCH PPS market basket, including any statutory adjustments. Consistent with our historical practice, for FY 2016, we are applying the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2016, we also are making certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2016 LTCH PPS standard Federal payment rate, as we proposed, we are applying 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). We also, as proposed, used more recent data to determine the update to the LTCH PPS standard Federal payment rate for FY 2016 in this final rule.

For FY 2015, we established an annual update to the LTCH PPS standard Federal rate of 2.2 percent for FY 2015 based on the full estimated LTCH PPS market basket increase of 2.9 percent, less the MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.2 percentage point required by

sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xi), we established an annual update to the standard Federal rate for FY 2015 of 2.2 percent. That is, we applied an update factor of 1.022 to the FY 2014 Federal rate of $40,607.31 to determine the FY 2015 standard Federal rate. The standard Federal rate for FY 2015 was further adjusted by an adjustment factor of 0.98734 for FY 2015 under the final year of the 3-year phase-in of the one-time prospective adjustment at § 412.523(d)(3)(ii). We also applied an area wage level budget neutrality factor for FY 2015 of 1.0016703 to the standard Federal rate to ensure that any changes to the area wage level adjustment would not result in any change in estimated aggregate LTCH PPS payments. Consequently, we established a standard Federal rate for FY 2015 of $41,043.71 (calculated as $40,607.31 × 1.022 × 0.98734 × 1.001670) (79 FR 50392).

In this final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.7 percent, which was determined consistent with our proposal and using the methodology previously described. Accordingly, under § 412.523(c)(3)(xii), we are applying a factor of 1.017 to the FY 2015 standard Federal rate of $41,043.71 to determine the FY 2016 LTCH PPS standard Federal payment rate. These factors are based on IGI's second quarter 2015 forecast, which are the best available data at this time. For LTCHs that fail to submit quality reporting data for FY 2016 under the LTCH QRP, under § 412.523(c)(3)(xii), applied in conjunction with the provisions of § 412.523(c)(4), we are reducing the annual update to the LTCH PPS standard Federal payment rate by an additional 2.0 percentage points consistent with section 1886(m)(5) of the Act. In those cases, the LTCH PPS standard Federal payment rate is updated by -0.3 percent (that is, a update factor of 0.997) for FY 2016 for LTCHs that fail to submit the required quality reporting data for FY 2016 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we also are applying an area wage level budget neutrality factor to the FY 2016 LTCH PPS standard Federal payment rate of 1.000513, which was determined using the methodology previously described. We are applying this area wage level budget neutrality factor to the FY 2016 LTCH PPS standard Federal payment rate to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index values and labor-related share) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are establishing a LTCH PPS standard Federal payment rate of $41,762.85 (calculated as $41,043.71 × 1.017 × 1.000513) for FY 2016. For LTCHs that fail to submit quality reporting data for FY 2016 in accordance with the requirements of the LTCHQRP under section 1886(m)(5) of the Act, we are establishing a LTCH PPS standard Federal payment rate of $40,941.55 (calculated as $41,043.71 × 0.997 × 1.000513) for FY 2016. We note, as discussed in section VII.B. of the preamble of this final rule, under our application of the site neutral payment rate required under section 1886(m)(6) of the Act, this LTCH PPS standard Federal payment rate will only be 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).

B. Adjustment for Area Wage Levels for the LTCH PPS Standard Federal Payment Rate for FY 2016

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 rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal 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.

When we implemented the LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH area wage index values are the full LTCH PPS area wage index values calculated based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56015 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. 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 (MSAs) (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.

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 new OMB labor market area delineations based on the 2010 Decennial Census data. We made these revisions because we believe that these OMB delineations 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. At the time of the development of this proposed rule, OMB had not issued any further updates subsequent to OMB Bulletin No. 13–01, which was dated February 28, 2013, and established

revised delineations based on 2010 Census Bureau data that were subsequently adopted in the FY 2015 IPPS/LTCH PPS final rule. (The OMB bulletins are available on the OMB Web site at: *http://www.whitehouse.gov/omb*. Go to ''Information For Agencies'' and click on ''Bulletins''.) Therefore, for FY 2016, as proposed, we are continuing to use the CBSA-based labor market area delineations currently used under the LTCH PPS (as adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185)). We believe that these 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.

3. 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 PPS Federal prospective 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 (Wages and Salaries; Employee Benefits; Professional Fees Labor-Related, Administrative and Business Support Services; and All-Other: Labor-Related Services) 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 and the development of the RPL market basket 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 revised and rebased the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. In addition, we determined the labor-related share for FY 2013 as the sum of the FY 2013 relative importance of each labor-related cost category of the FY 2009-based LTCH-specific market basket. For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479). Consistent with our historical practice, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50393 through 50394), we determined the LTCH PPS labor-related share for FY 2015 based on the FY 2015 relative importance of each labor-related cost category, which reflected the different rates of price change for these cost categories between the base year (FY 2009) and FY 2015. Specifically, based on IGI's second quarter 2014 forecast of the FY 2009-based LTCH-specific market basket, we established a labor-related share under the LTCH PPS for FY 2015 of 62.306 percent.

For FY 2016, we are establishing a labor-related share for the LTCH PPS standard Federal payment rate payments based on IGI's second quarter 2015 forecast of the FY 2009-based LTCH-specific market basket. Consistent with our historical practice, as proposed, we also are using more recent data to determine the final FY 2016 labor-related share. In addition, as proposed, we are specifying the labor-related share to one decimal place, which is consistent with the IPPS labor-related share and the LTCH market basket update. The following table shows the FY 2016 labor-related share relative importance using IGI's second quarter 2015 forecast of the FY 2009-based LTCH-specific market basket. The sum of the relative importance for FY 2016 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related, Administrative and Business Support Services; and All Other: Labor-Related Services) is 57.9 percent. We are establishing that the portion of capital-related costs that is influenced by the local labor market would continue to be estimated to be 46 percent. Because the relative importance for capital-related costs would be 9.0 percent of the FY 2009-based LTCH-specific market basket in FY 2016, we are taking 46 percent of 9.0 percent to determine the labor-related share of capital-related costs for FY 2016, which would result in 4.1 percent (0.46×9.0). We then added that 4.1 percent for the capital-related cost amount to the 57.9 percent for the operating cost amount to determine the total labor-related share for FY 2016. Therefore, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are establishing a labor-related share under the LTCH PPS for FY 2016 of 62.0 percent. Consistent with our proposal, this labor-related share is determined using the same methodology as used in calculating all previous fiscal years LTCH labor-related shares.

FY 2016 LABOR-RELATED SHARE RELATIVE IMPORTANCE BASED ON THE FY 2009-BASED LTCH-SPECIFIC MARKET BASKET

	FY 2016 Labor-related share relative importance
Wages and Salaries	44.6
Employee Benefits	8.1
Professional Fees: Labor-Related	2.2
Administrative and Business Support Services	0.5
All Other: Labor-Related Services	2.5
Subtotal	57.9
Labor-Related Portion of Capital Costs (46 percent)	4.1
Total Labor-Related Share	62.0

4. Wage Index for FY 2016 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 2015 LTCH PPS final rule (79 FR 50394 through 50396), we calculated the FY 2015 LTCH PPS area wage index values using the same data used for the FY 2015 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2011), 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 2015 LTCH PPS area wage index values consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time, and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for

areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2016 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, as we proposed, we are using wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2012, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We are using FY 2012 wage data because these data are the most recent complete data available. We also note that these are the same data used to compute the FY 2016 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule. We are computing the FY 2016 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, labor market area delineations, as previously discussed in section V.B.2. 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, as we proposed. We also are, as we proposed, continuing 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, under our methodology for determining the FY 2016 LTCH PPS standard Federal payment rate area wage index values, as we proposed, we are continuing 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 2012 IPPS wage data that we are using to determine the FY 2016 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the FY 2016 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 final rule and available via the Internet on the CMS Web site). 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 2012 IPPS wage data that we are using to determine the FY 2016 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS standard Federal payment rate wage index value for rural areas with no IPPS wage data for FY 2016. 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 FY 2016 LTCH PPS standard Federal payment rate wage index values that are applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2015, through September 30, 2016, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site.

5. 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 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 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 final rule, for FY 2016 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), as we proposed, we are applying an area wage level adjustment budget neutrality factor to adjust the standard Federal rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, as we proposed, we are determining an area wage level adjustment budget neutrality factor that will be applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2016 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2015 wage index values, including the 50/50 blended area wage index values, as applicable, and the FY 2015 labor-related share of 62.306 percent (as established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50393 and 50397).

Step 2—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2016 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this final rule and available via the Internet on the CMS Web site) and the FY 2016 labor-related share of 62.0 percent (based on the latest available data as previously discussed previously 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 2015 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the FY 2016 area wage level adjustments (calculated in Step 2) to determine the area wage level adjustment budget

neutrality factor for FY 2016 LTCH PPS standard Federal payment rate payments.

Step 4—We then applied the FY 2016 area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2016 LTCH PPS standard Federal payment rate after the application of the FY 2016 annual update (discussed previously in section V.A.2. of this Addendum).

We note that, with the exception of cases subject to the transitional blend payment rate provisions in the first 2 years, 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) will be 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 were in effect at the time of discharge to calculate the FY 2016 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor described above. (For additional information on our application of site neutral payment rate required under section 1886(m)(6) of the Act, we refer readers to section VII.B. of the preamble of this final rule.)

For this final rule, using the steps in the methodology described above, we determined a FY 2016 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.000513. Accordingly, in section V.A.2. of the Addendum to this final rule, to determine the FY 2016 LTCH PPS standard Federal payment rate, we are applying an area wage level adjustment budget neutrality factor of 1.000513, in accordance with § 412.523(d)(4). The FY 2016 LTCH PPS standard Federal payment rate shown in Table 1E of the Addendum to this final rule reflects this adjustment factor.

C. 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 described above.

Under our current methodology, we update the COLA factors for Alaska and Hawaii every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) (77 FR 53712 through 53713). This methodology 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. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii, we refer readers to section VII.D.3. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482).)

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. Under our current policy, we update the COLA factors using the methodology described above every 4 years; the first year began in FY 2014 (77 FR 53482). Therefore, in this final rule, as we proposed, for FY 2016, 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 continuing to use the COLA factors based on the 2009 OPM COLA factors updated through 2012 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 2014 IPPS/LTCH PPS final rule. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50998) for a discussion of the FY 2014 COLA factors.) Consistent with our historical practice and as we proposed, we are establishing 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).

COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS UNDER THE LTCH PPS FOR FY 2016

Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
All other areas of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. Overview

a. Background

Under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of the BIPA, in the regulations at § 412.525(a), we established an adjustment for additional payments for outlier cases that have extraordinarily high costs relative to the costs of most discharges. We refer to these cases as high cost outliers (HCOs). Providing additional payments for outliers strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. These additional payments reduce the financial losses that would otherwise be incurred when treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. Under our current HCO policy at § 412.525(a), we set the outlier threshold before the beginning of the applicable rate year so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS.

Under the current HCO policy, we make outlier payments for any discharges if the estimated cost of a case exceeds the adjusted payment under the LTCH PPS standard Federal payment rate plus a fixed-loss amount. Specifically, in accordance with existing § 412.525(a)(3), we make an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the patient case and the outlier threshold, which is the sum of the adjusted payment under the

LTCH PPS standard Federal payment rate and the fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that a hospital incurs under the outlier policy for a case with unusually high costs before the LTCH will receive any additional payments. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. Under the current LTCH PPS HCO policy, the LTCH's loss is limited to the fixed-loss amount and a fixed percentage of costs above the outlier threshold (the adjusted LTCH PPS standard Federal payment rate payment plus the fixed-loss amount). The fixed percentage of costs is called the marginal cost factor. We calculate the estimated cost of a case by multiplying the Medicare allowable covered charge by the hospital's overall hospital cost-to-charge ratio (CCR).

Under the current HCO policy at § 412.525(a), we determine a fixed-loss amount, that is, the maximum loss that an LTCH can incur under the LTCH PPS for a case with unusually high costs before the LTCH will receive any additional payments. We calculate the fixed-loss amount by estimating aggregate payments with and without an outlier policy. The fixed-loss amount results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments. Currently, MedPAR claims data and CCRs based on data from the most recent Provider-Specific File (PSF) (or from the applicable statewide average CCR if an LTCH's CCR data are faulty or unavailable) are used to establish a fixed-loss threshold amount under the LTCH PPS.

b. Application of the Site Neutral Payment Rate

Section 1206 of Public Law 113–67 establishes a new dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges, beginning in FY 2016. To implement this statutory change, as discussed in section VII.B. of the preamble of this final rule, we will pay hospitals for LTCH discharges that meet the criteria for exclusion from site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) based on the LTCH PPS standard Federal payment rate, which includes HCO payments determined under existing § 412.525(a). Furthermore, we are establishing that 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 adjustments, such as outlier payments), or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2), consistent with the statute.

Under the new dual rate LTCH PPS payment structure, as discussed in section VII.B.7.b. of the preamble of this final rule, as we proposed, we are establishing two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. We are revising the regulations by making changes to the HCO policy to account for the new dual rate LTCH PPS payment structure by revising paragraphs (a)(1), (a)(2), and (a)(3), and adding a new paragraph (a)(4) to existing § 412.525 of the regulations. Under our HCO policy revised in accordance with the new dual rate LTCH PPS payment structure, we are establishing a fixed-loss amount and target for LTCH PPS standard Federal payment rate cases using the current LTCH PPS HCO policy, but limiting 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. Therefore, we are not making any modifications to the HCO methodology as it applies to LTCH PPS standard Federal payment rate cases other than determining a fixed-loss amount using only data from LTCH PPS standard Federal payment rate cases. Specifically, under our finalized policy, LTCH PPS standard Federal payment rate cases will receive an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which is the sum of the LTCH PPS payment for the LTCH PPS standard Federal payment rate case and the fixed-loss amount for such cases. The fixed-loss amount for LTCH PPS standard Federal payment rate cases will continue to be determined so that estimated HCO payments would be projected to be equal to 8 percent of estimated total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

Furthermore, as we proposed, we are revising the HCO policy under existing § 412.525(a) to provide for high-cost outlier payments under the site neutral payment rate. Specifically, we are establishing that site neutral payment rate cases will receive an additional payment for HCOs that is equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold for site neutral payment rate discharges, which we are establishing as the sum of site neutral payment rate for the case and the IPPS fixed-loss amount. In addition, in order to maintain budget neutrality, as we proposed and as discussed in section VII.B.7.b. of the preamble of this final rule, we are making the HCO payments for site neutral payment rate cases budget neutral by applying a budget neutrality factor to the LTCH PPS payments for those site neutral payment rate cases. (Additional details on the calculation of the budget neutrality adjustment for HCO payments to site neutral payment rate cases is discussed subsequently in section V.D.4. of this Addendum.)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

The following is a discussion of CCRs that are used in determining payments for HCO cases under § 412.525(a), SSO cases paid under the LTCH PPS in accordance with § 412.529, and site neutral payment rate cases paid in accordance with proposed § 412.522(c) (as discussed in section VII.B.4. of the preamble of this final rule). Although this section is specific to HCO cases, because CCRs and the policies and methodologies pertaining to them are used in determining payments for HCO, SSO, and site neutral payment rate cases (to determine the estimated costs of these cases), we are discussing the determination of CCRs under the LTCH PPS for these three types of cases simultaneously in this section.

In determining HCO payments in accordance with § 412.525(a), SSO payments in accordance with § 412.529 and site neutral payment rate payments in accordance with § 412.522(c), we calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. In general, we use the LTCH's overall CCR, which is computed based on either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period, in accordance with § 412.525(a)(4)(iv)(B), for HCOs, § 412.529(f)(4)(ii) for SSOs, and § 412.522(c)(1)(ii) for site neutral payment rate cases. (We note that, in some instances under the provisions of the regulations at § 412.525(a)(4)(iv) and § 412.529(f)(4), and § 412.522(c)(1)(ii), we may use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or that is requested by the hospital.) Under the LTCH PPS, a single prospective payment per discharge is made for both inpatient operating and capital-related costs. Therefore, we compute a single ''overall'' or ''total'' LTCH-specific CCR 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 charges. Specifically, an LTCH's CCR is calculated by dividing an LTCH's total Medicare costs (that is, the sum of its operating and capital inpatient routine and ancillary costs) by its total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges).

b. LTCH Total CCR Ceiling

Generally, an LTCH is assigned the applicable statewide average CCR if, among other things, an LTCH's CCR is found to be in excess of the applicable maximum CCR threshold (that is, the LTCH CCR ceiling). This is because CCRs above this threshold 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. Therefore, under our established policy, generally, if an LTCH's calculated CCR is above the applicable ceiling, the applicable LTCH PPS statewide average CCR is assigned to the LTCH instead of the CCR computed from its most recent (settled or tentatively settled) cost report data.

In this final rule, using our established methodology for determining the LTCH total CCR ceiling, based on IPPS total CCR data from the March 2015 update of the PSF, we are establishing a total CCR ceiling of 1.335 under the LTCH PPS for FY 2016 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCOs, § 412.529(f)(4)(iii)(B) for SSOs, and § 412.522(c)(1)(ii) for site neutral payment rate cases. We also are, as proposed, using more recent data to determine the LTCH PPS CCR ceiling for this FY 2016 final rule.

c. LTCH Statewide Average CCRs

Our general methodology established for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling (described above) because it is based on ''total'' IPPS CCR data. Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C) the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate policy 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 (for this purpose, consistent with current policy, 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 CCR is in excess of the LTCH 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 and as we proposed, in this final rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the March 2015 update of the PSF, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2015 through September 30, 2016, in Table 8C listed in section VI. of the Addendum to this final rule (and available via the Internet). We also, as proposed, are using more recent data to determine the LTCH PPS statewide average total CCRs for FY 2016.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut and Massachusetts have areas that are designated as rural, there are no short-term, acute care IPPS hospitals or LTCHs located in those areas as of March 2015. Therefore, consistent with our existing methodology and as we proposed, we are using the national average total CCR for rural IPPS hospitals for rural Connecticut and Massachusetts in Table 8C listed in section VI. of the Addendum to this final rule (and available via the Internet). In addition, consistent with our existing methodology as we proposed, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are continuing 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 and SSO Payments

Under the HCO policy at § 412.525(a)(4)(iv)(D) and the SSO policy at § 412.529(f)(4)(iv), the payments for HCO and SSO, cases are subject to reconciliation. Specifically, any reconciliation of payments is based on the CCR that is calculated based on a ratio of cost-to-charge data computed from the relevant cost report determined at the time the cost report coinciding with the discharge is settled. (As discussed section VII.B.4.a. of the preamble of this final rule, after consideration of public comments we received, we are not finalizing our proposal to establish a reconciliation process for site neutral payment rate payments. However, we are finalizing the portion of our proposal to apply the existing HCO reconciliation policy to the HCO payments made to site neutral payment rate cases. For additional information on the existing 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. Establishment of the LTCH PPS Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2016

When we implemented the LTCH PPS, under the broad authority of section 123 of the BBRA as amended by section 307(b) of BIPA, 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). To determine the fixed-loss amount, we estimate outlier payments and total LTCH PPS payments for each case using claims data from the MedPAR files. Specifically, we estimate the cost of the

case by multiplying the Medicare covered charges from the claim by the LTCH's CCR. Under the HCO policy at § 412.525(a), if the estimated cost of the case exceeds the outlier threshold, we make an outlier payment equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (that is, the sum of the adjusted standard Federal rate payment and the fixed-loss amount).

As noted above and as discussed in greater detail in section VII.B.7.b. of the preamble of this final rule, under the new dual rate LTCH PPS payment structure, we are establishing two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. Under this finalized policy, for LTCH PPS standard Federal payment rate cases, we are establishing a fixed-loss amount and target using the current LTCH PPS HCO policy, but to limit the data used under that policy to LTCH cases that would have been paid as LTCH PPS standard Federal payment rate cases, if that payment rate had been in effect at the time of those discharges. Therefore, as we proposed, we are not making any modifications to the existing LTCH PPS HCO payment methodology as it applies to LTCH PPS standard Federal payment rate cases, other than determining a fixed-loss amount using only data from LTCH PPS standard Federal payment rate cases (or cases that would have been LTCH PPS standard Federal payment rate cases had the new dual rate LTCH PPS payment structure been in effect at the time of those discharges). As such, LTCH PPS standard Federal payment rate cases will continue to receive an additional payment for any HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which is the sum of the LTCH PPS payment for the LTCH PPS standard Federal payment rate case and the fixed-loss amount. The fixed-loss amount for LTCH PPS standard Federal payment rate cases will continue to be determined so that estimated HCO payments would be projected to equal 8 percent of estimated total LTCH PPS standard Federal payment rate cases, and a budget neutrality factor will continue to be applied to LTCH PPS standard Federal payment rate cases to offset that 8 percent so that HCO payments for LTCH PPS standard Federal payment rate cases will be budget neutral. Below we present our calculation of the LTCH PPS fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2016, which is consistent with the methodology used to establish the FY 2015 LTCH PPS fixed-loss amount. (Additional discussion of our HCO payment policy proposals for site neutral payment rate cases is discussed subsequently in section V.D.4. of this Addendum.)

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50399 through 50400), we presented our policies regarding the methodology and data we used to establish a fixed-loss amount of $14,972 for FY 2015, which was calculated using our existing methodology (based on the data and the rates and policies presented in that final rule) in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. Consistent with our historical practice of using the best data available, in determining the fixed-loss amount for FY 2015, we used the most recent available LTCH claims data and CCR data, that is, LTCH claims data from the March 2014 update of the FY 2013 MedPAR file and CCRs from the March 2014 update of the PSF, as these data were the most recent complete LTCH data available at that time.

In this final rule, as we proposed, we are continuing to use our existing methodology to calculate a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2016 using the best available data that will maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the rates and policies for these cases presented in this final rule). Specifically, based on the most recent complete LTCH data available (that is, LTCH claims data from the March 2015 update of the FY 2014 MedPAR file and CCRs from the March 2015 update of the PSF), we determined a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2016 that will result in estimated outlier payments projected to be equal to 8 percent of estimated FY 2016 payments for such cases. Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are establishing a fixed-loss amount of $16,423 for LTCH PPS standard Federal payment rate cases for FY 2016. We also will 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 adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $16,423).

We note that the fixed-loss amount of $16,423 for FY 2016 for LTCH PPS standard Federal payment rate cases is lower than the proposed FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $18,768. This decrease is primarily a result of updated data used to calculate the fixed-loss amount in this final rule, such as the most recent available LTCH claims data in the MedPAR file, CCRs in the PSF, and the estimate of the LTCH market basket increase. We also note that the fixed-loss amount of $16,423 for LTCH PPS standard Federal payment rate cases for FY 2016 is higher than the FY 2015 fixed-loss amount of $14,792. This increase is largely attributable to the implementation of the new dual rate LTCH PPS payment structure, under which we have established separate HCO target amounts for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases. The FY 2015 fixed-loss amount was determined based on data from all LTCH cases—both those that would have been paid as site neutral payment rate cases and those that would have been paid as LTCH PPS standard Federal payment rate cases if the new dual rate LTCH PPS payment structure had been in effect at that time. However, under our finalized policy, the fixed-loss amount of $16,423 for FY 2016 will only be used to determine HCO payments made for LTCH PPS standard Federal payment rate cases. We currently estimate that the FY 2015 fixed-loss amount of $14,972 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 8.1 percent of total estimated FY 2015 LTCH PPS payments to those cases, which exceeds the 8 percent target. Therefore, we believe that it is necessary and appropriate to increase the fixed-loss amount to maintain that, for LTCH PPS standard Federal payment rate cases, estimated HCO payments would equal 8 percent of estimated total LTCH PPS payments for those cases as required under the revisions to § 412.525(a). (For further information on the existing 8 percent HCO ''target'' requirement, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024).) Maintaining the fixed-loss amount at the current level would result in HCO payments that are more than the current regulatory 8-percent target that we are applying to total payments for LTCH PPS standard Federal payment rate cases because a lower fixed-loss amount would result in more cases

qualifying as outlier cases, as well as higher outlier payments for qualifying HCO cases because the maximum loss that an LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be smaller.

b. Application of the High-Cost Outlier Policy to SSO Cases

Under our finalized policies to implement the new dual rate LTCH PPS payment structure required by statute, we are establishing that LTCH PPS standard Federal payment rate cases (that is, LTCH discharges that meet the criteria for exclusion from the site neutral payment rate) will continue to be paid based on the LTCH PPS standard Federal payment rate, and will include all of the existing payment adjustments under § 412.525(d), such as the adjustments for SSO cases under § 412.529. (For additional information on our payments for LTCH PPS standard Federal payment rate cases, we refer readers to section VII.B.4.c. of the preamble of this final rule.) Under some rare circumstances, an LTCH discharge can qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case, as discussed in the August 30, 2002 final rule (67 FR 56026). In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS–LTC–DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO payment plus the fixed-loss amount), the discharge is eligible for payment as an HCO. Therefore, for an SSO case in FY 2016, the HCO payment will be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the fixed-loss amount of $16,423 and the amount paid under the SSO policy as specified in § 412.529).

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Under the new dual rate LTCH PPS payment structure, the statute establishes two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, as discussed in section VII.B. of the preamble of this final rule, we will pay for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) based on the LTCH PPS standard Federal payment rate. In addition, consistent with the statute, we are establishing that 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). Furthermore, we are establishing two separate HCO targets-one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases.

For site neutral payment rate cases, as we proposed, we are establishing that such cases will 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. We are establishing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. As discussed in section II.A.4.g.(1) of this Addendum, we are establishing a fixed-loss amount of $22,544 under the IPPS for FY 2016. Accordingly, under our finalized policies, for FY 2016 we will calculate HCO payments for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the fixed-loss amount for site neutral payment rate cases of $22,544). (We note that, as discussed in section VII.B.7.b. of the preamble of this final rule, in light of our HCO policies and in accordance with our implementation of the new dual rate LTCH PPS payment structure, any site neutral payment rate case that is paid 100 percent of the estimated cost of the case (because that amount is lower than the IPPS comparable per diem amount) will not be eligible to receive a HCO payment because, by definition, the estimated costs of such cases would never exceed the IPPS comparable per diem amount by any threshold.)

Furthermore, under our finalized policy, after consideration of public comments as discussed in section VII.B.7.b. of the preamble of this final rule, we are establishing that HCO payments for site neutral payment rate cases will be budget neutral, such that the site neutral payment rate HCO payments will not result in any change in estimated aggregate LTCH PPS payments (For additional details on our HCO policy for site neutral payment rate cases, we refer readers to section VII.B.7.b. of the preamble of this final rule.) In order to achieve this, in the proposed rule (80 FR 24648 through 24649), under proposed new § 412.522(c)(2)(i), we proposed to apply a budget neutrality factor to the payments for all site neutral payment rate cases, which would be established on an estimated basis. In addition, in order to estimate the magnitude a budget neutrality adjustment for HCO payments for site neutral payment rate cases, we relied on the assumption by our actuaries that site neutral payment rate cases would have lengths of stay and costs comparable to IPPS cases assigned to the same MS–DRG. Because site neutral payment rate cases are expected to have lengths of stay and costs comparable to IPPS cases assigned to the same MS DRG, we project that our policy to use the IPPS fixed-loss threshold for the site neutral payment rate cases will result in HCO payments for site neutral payment rate cases that are similar in proportion as is seen in IPPS cases assigned to the same MS–DRG; that is, 5.1 percent. Therefore, under new § 412.522(c)(2)(i), we proposed to adjust all payments for site neutral payment rate cases by a budget neutrality factor so that the estimated HCO payments payable for site neutral payment rate cases do not result in any increase in aggregate LTCH PPS payments. That is, for FY 2016 we proposed to apply a budget neutrality adjustment for estimated HCO payments for site neutral payment rate cases to *both* the site neutral payment rate and the LTCH PPS standard Federal payment rate portions of the FY 2016 transitional blended rate paid to site neutral payment rate cases. (We refer readers to section VII.B.7.b. of this preamble for our discussion of the public comments we received, our responses to those comments, and our finalized policy for a budget neutrality requirement for site neutral payment rate cases' HCO payments.) Because the statutory LTCH PPS payment changes required by section 1886(m)(6) of the Act (that is, the application of the site neutral payment rate) are effective for LTCH PPS discharges occurring in cost reporting periods beginning on or after October 1, 2015, in the proposed rule, our site neutral payment rate case HCO budget neutrality calculations also included a proposed approach to account for when LTCHs' first cost reporting period begins on or after October 1, 2015.

Under our proposed approach (summarized above and described in more detail in section V.D.4. of the Addendum of the proposed rule (80 FR 24649)) and based on the site neutral payment rate LTCH cases in our database from the FY 2014 MedPAR files (that is, cases that would have met

the new criteria had they been in effect at the time of the discharge), we estimated that site neutral payment rate HCO payments would be approximately 2.3 percent of total LTCH PPS payments for site neutral payment rate cases in FY 2016. Accordingly, we proposed to applying a budget neutrality factor of 0.976996 to all payments for site neutral payment rate cases in FY 2016 so that the estimated HCO payments payable to those cases would not result any increase in aggregate LTCH PPS payments.

Comment: Several commenters disagreed with our proposed approach of adjusting *all* payments for site neutral payment rate cases in FY 2016 (that is, *both* the site neutral payment rate and the LTCH PPS standard Federal payment rate portions of the transitional blended rate payment) by a budget neutrality factor for estimated HCO payments payable to site neutral payment rate cases. The reasons for the commenters' opposition to this proposal include: The LTCH PPS standard Federal payment rate portion under transitional blended rate would be lower than the LTCH PPS standard Federal payment rate used to pay cases that are excluded from the site neutral payment rate; and the comingling of site neutral payment rate and LTCH PPS standard Federal payment rate elements unnecessarily convolutes the proposed site neutral payment rate HCO calculations. Consequently, these commenters recommended that, if CMS finalizes its proposal to apply a budget neutrality factor to account for estimated site neutral payment case HCO payments, the site neutral payment rate and the LTCH PPS standard Federal payment rate portions of the transitional blended rate should be treated separately. That is, the budget neutrality adjustment for estimated HCO payments to site neutral payment rate cases should only be applied to the site neutral payment rate portion of the transitional blended rate payment (and not applied to the LTCH PPS standard Federal payment rate portion of the transitional blended rate payment).

Furthermore, some commenters stated that the description of the calculation of the estimated percentage of site neutral payment rate case HCO payments for FY 2016 was too brief, and requested that CMS provide additional details on the steps used to calculate the budget neutrality adjustment for estimated HCO payments to site neutral payment rate cases. In addition, commenters believed that our proposed calculation of our estimate in the proposed rule of HCO payments to site neutral payment rate cases includes a technical error. That is, the commenters stated that the calculation of the percentage of estimated site neutral payment rate case HCO payments for FY 2016 of 2.3 percent appears to be based on estimated HCO payments for site neutral payment rate cases *before* applying the transitional blended rate payment (rather than only 50 percent, consistent with the calculation of the transitional blended rate that is comprised of only 50 percent of the site neutral payment rate payment amount). Lastly, some commenters agreed with the proposed approach to account for when LTCHs' first cost reporting period begins on or after October 1, 2015 in estimating site neutral payment rate payments in FY 2016.

Response: We agree that the approach recommended by commenters would lessen the complexity and increase the transparency of the calculation of the site neutral payment rate HCO payment budget neutrality adjustment. Such an approach simplifies the calculation because the adjustment to account for additional HCO payments to site neutral payment rate cases would only be applied to the portion of the blended rate payment that is based on the site neutral payment rate calculation under new § 412.522(c)(1). Therefore, after consideration of public comments we received, we are modifying our proposal by adopting the commenters' recommended approach of applying the budget neutrality adjustment for estimated HCO payments for site neutral payment rate cases only to the site neutral payment rate portion of the transitional blended rate payment. As a result of this modification, we are making conforming changes to our proposed codification of this policy under new § 412.522(c)(2)(i) to specify that the site neutral payment rate HCO budget neutrality adjustment does not include the portion of the blended payment rate described in new § 412.522(c)(3)(ii).

This modification to our proposed approach for applying the budget neutrality adjustment to the site neutral payment rate portion of the transitional blended rate payment eliminates the need to perform any calculation of the site neutral payment rate cases HCO payment budget neutrality adjustment under our finalized policy. This is, as discussed above and in greater detail in section VII.B.7.b. of the preamble of this final rule, because based on our actuarial assumptions we project that our finalized policy to use the IPPS fixed-loss threshold for the site neutral payment rate cases will result in HCO payments for those cases that are similar in proportion as is seen in IPPS cases assigned to the same MS–DRG; that is, 5.1 percent. In other words, we estimated that HCO payments for site neutral payment rate cases will be 5.1 percent of the site neutral payment rate payments. As noted above, payments to site neutral payment rate cases in FY 2016 will be paid under the blended transitional rate. As such, estimated HCO payments for site neutral payment rate cases in FY 2016 under our finalized policies are equal to 5.1 percent of the portion of the blended rate payment that is based on the estimated site neutral payment rate payment amount (and does not include the LTCH PPS standard Federal payment rate payment amount, as we proposed). Therefore, to ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2016 do not result any increase in estimated aggregate FY 2016 LTCH PPS payments, it is necessary to reduce the site neutral payment rate portion of the blended rate payment by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2016. In order to achieve this, under § 412.522(c)(2)(i) for FY 2016, we are applying 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). (We note, because this adjustment is intended to ensure that estimated HCO payments payable to site neutral payment rate cases are budget neutral (that is, do not result in any increase in aggregate LTCH PPS payments), the magnitude of the reduction is larger than it would be under our proposed approach as the adjustment is now only being applied to half of the transitional blended rate payment (rather than the whole transitional blended rate payment as it was under our proposal).

Upon review of our calculation in the proposed rule of the estimated percentage of site neutral payment rate case HCO payments for FY 2016, we determined that our calculation of the proposed budget neutrality adjustment for estimated HCO payments for site neutral payment rate cases inadvertently contained the technical error pointed out by the commenters. We appreciate the commenters bringing that inadvertent error to our attention, and we have included the necessary correction in the calculation of our estimate of HCO payments for site neutral payment rate cases, which we discuss in the regulatory impact analyses presented in section I.J. of Appendix A of this final rule. (We note, as explained above, the modification to the proposed approach for applying the

budget neutrality adjustment for estimated HCO payments for site neutral payment rate cases that we are adopting in this final rule eliminates the need for calculation of the budget neutrality adjustment under our finalized policy.)

We appreciate the commenters' support of our proposed approach to account for the fact that LTCHs whose cost reporting periods begin on or after October 1, 2015, will receive the LTCH PPS standard Federal payment rates for all of their LTCH PPS cases, including their cases that would be site neutral payment rate cases, until the start of their next cost reporting period when estimating site neutral payment rate payments in FY 2016. Because we are adopting a different, more direct approach in this final rule (as discussed above), in the applying the budget neutrality requirement for estimated HCO payments payable to site neutral payment rate cases in for FY 2016, it is no longer necessary to account for when LTCHs' first cost reporting period begins on or after October 1, 2015 (as we did to calculate the budget neutrality adjustment under our proposed approach). We note, however, for purposes of the impact analyses presented in section I.J. of Appendix A of this final rule, to estimate site neutral payment rate payments for FY 2016, it is still necessary to account for when LTCHs' first cost reporting period begins on or after October 1, 2015. Accordingly, in this final rule, when estimating total LTCH PPS site neutral payment rate payments in Federal FY 2016, as we proposed, we are applying an adjustment to account for the varying effective dates of the new dual rate LTCH PPS payment structure. We describe our application of this approach for purposes of the impact analyses presented in this final rule in section I.J. of Appendix A of this final rule. (For a description of our proposed approach to account for the statutory rolling effective date of the revisions to the LTCH PPS, we refer readers to section V.D.4. of the Addendum of the proposed rule (80 FR 24649).)

In summary, after consideration of public comments we received, for the reasons discussed above, we are modifying our proposed application of the site neutral payment rate HCO payment budget neutrality adjustment. In this final rule, we are adopting an approach under which the budget neutrality adjustment for estimated HCO payments to site neutral payment rate cases will be applied to the site neutral payment rate portion of the transitional blended rate payment in FY 2016 (and will not applied to the LTCH PPS standard Federal payment rate portion of the transitional blended rate payment). Accordingly, to ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2016 do not result any increase in estimated aggregate FY 2016 LTCH PPS payments, we are reducing the site neutral payment rate portion of the blended rate payment in FY 2016 by 5.1 percent. In order to achieve this, we are applying a budget neutrality factor of 0.949 to the site neutral payment rate portion of the blended rate payment in FY 2016, in accordance with new § 412.522(c)(2)(i).

E. 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, we established a policy for reflecting the changes to the Medicare IPPS DSH payment adjustment methodology provided for 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 under the age of 65 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 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. As explained in the FY 2014 IPPS/LTCH PPS final rule (79 FR 50766 through 50767), 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.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50400 through 50401), we discussed that, for FY 2015, based on the latest data available at that time, we projected that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the proposed payments for uncompensated care under section 1886(r)(2) of the Act, would result in overall Medicare DSH payments equaling 85.26 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of amendments made by the Affordable Care Act. Therefore, the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.534 and § 412.536 for FY 2015 includes an applicable operating Medicare DSH payment amount that would be equal to 85.26 percent of the operating Medicare DSH payment amount based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act.

For FY 2016, as discussed in greater detail in section IV.D.3.d.(2) of the preamble of this final 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 63.69 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 of uncompensated care payments that will be made to eligible IPPS hospitals in FY 2016. In other words, Medicare DSH payments prior to the amendments made by the Affordable Care Act will be adjusted to 47.77 percent (the product of 75 percent and 63.69 percent) and the resulting amount will be used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2016, 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 72.77 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of amendments made by the Affordable Care Act (that is, 25 percent + 47.77 percent = 72.77 percent).

As we proposed and consistent with our historical practice of using the most recent data available, in this final rule, for FY 2016, we are establishing that the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.534 and § 412.536 will include an applicable operating Medicare DSH payment amount that is equal to 72.77 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula but for the amendments made by the Affordable Care Act.

F. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2016

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the new dual rate LTCH PPS payment structure that begins in FY 2016, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate will be paid based on the LTCH PPS standard Federal payment rate (as discussed in section VII.B. of the preamble of this final rule). Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment for a case by the applicable LTCH PPS wage index (FY 2016 values are shown in Tables 12A through 12B listed in section VI. of the Addendum of this final rule and are available via the Internet). The LTCH PPS standard Federal payment is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the FY 2016 factors are shown in the chart in section V.D. of this Addendum) in accordance with § 412.525(b). In this final rule, we are establishing an LTCH PPS standard Federal payment rate for FY 2016 of $41,762.85, as discussed in section V.A.2. of the Addendum to this final rule. We illustrate the methodology to adjust the LTCH PPS standard Federal payment rate for FY 2016 in the following example:

Example:

During FY 2016, 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 FY 2016 LTCH PPS wage index value for CBSA 16974 is 1.0401 (obtained from Table 12A listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2016 of 0.91548 (obtained from Table 11 listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site). The LTCH submitted quality reporting data for FY 2016 in accordance with the LTCHQRP 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 2016, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2016 LTCH PPS standard Federal payment rate ($41,762.85) by the labor-related share (62.0 percent) and the wage index value (1.0401). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (38.0 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which was then multiplied by the MS–LTC–DRG relative weight (0.9148) to calculate the total adjusted LTCH PPS standard Federal prospective payment for FY 2016 ($39,154.50). The table below illustrates the components of the calculations in this example.

LTCH PPS Standard Federal Prospective Payment Rate.	$41,762.85
Labor-Related Share	× 0.620
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate.	= $25,892.97
Wage Index (CBSA 16974) ..	× 1.0401
Wage-Adjusted Labor Share of LTCH PPS Standard Federal Payment Rate.	= $26,931.28
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($41,762.85 × 0.380).	+ $15,869.88
Adjusted LTCH PPS Standard Federal Payment Amount.	= $42,801.16
MS–LTC–DRG 189 Relative Weight.	× 0.9148
Total Adjusted LTCH PPS Standard Federal Prospective Payment.	= $39,154.50

VI. Tables Referenced in This Final Rule and Available Only Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this final 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 2015, for the FY 2016 rulemaking cycle, the IPPS and LTCH 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 be available only 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 section III.I. of the preamble to this final rule, we proposed to streamline and consolidate the wage index tables for FY 2016 and subsequent fiscal years. In previous fiscal years, the wage index tables have consisted of the following 12 tables: Table 2 (acute care hospitals' case-mix indexes; hospital wage indexes; hospital average hourly wages, and 3-year average of hospital average hourly wages); Table 3A (relevant fiscal year and 3-year average hourly wage for acute care hospitals in urban areas by CBSA); Table 3B (relevant fiscal year and 3-year average hourly wage for acute care hospitals in rural areas by CBSA); Table 4A (wage index and capital geographic adjustment factor (GAF) for acute care hospitals in urban areas by CBSA and by State); Table 4B (wage index and capital GAF for acute care hospitals in rural areas by CBSA and by State); Table 4C (wage index and capital GAF for acute care hospitals that are reclassified by CBSA and by State); Table 4D (States designated as frontier, with acute care hospitals receiving at a minimum the frontier State floor wage index; urban areas with acute care hospitals receiving

the statewide rural floor or imputed rural floor wage index); Table 4E (urban CBSAs and constituent counties for acute care hospitals); Table 4F (Puerto Rico wage index and capital GAF for acute care hospitals by CBSA); Table 4J (out-migration adjustment for acute care hospitals); Table 9A (hospital reclassifications and redesignations); and Table 9C (hospitals redesignated as rural under section 1886(d)(8)(e) of the Act). With the exception of Table 4E, we proposed to consolidate the information from the 11 other tables listed above into 2 new tables. The wage index tables provided in previous fiscal years either display information by CMS Certification Number (CCN) or by CBSA number. The new Table 2 contains information by CCN and information from the following tables that have been provided in previous fiscal years: Tables 2, 4J, 9A, and 9C. The new Table 3 contains information by CBSA and information from the following tables that have been provided in previous fiscal years: Tables 3A, 3B, 4A, 4B, 4C, 4D, and 4F. We believe these two new tables will be easier for the public to navigate and find all the relevant data and information from the tables provided in previous fiscal years. Finally, in previous fiscal years, Table 4E provided a list of urban CBSAs and constituent counties. Because of formatting technicalities, we found it difficult to consolidate the information from Table 4E into the two new tables. Therefore, we proposed to provide the data previously published as Table 4E for each annual proposed and final rule as one of our data files on our Web page (the same Web page where the county to CBSA crosswalk is posted).

We did not receive any public comments on our proposals for the tables. Therefore, we are finalizing our proposals to streamline and consolidate the wage index tables for FY 2016 and subsequent fiscal years by consolidating the information from the 11 tables listed above (excluding Table 4E) into 2 new tables. The new Table 2 contains information by CCN and information from the following tables that have been provided in previous fiscal years: Tables 2, 4J, 9A, and 9C. The new Table 3 contains information by CBSA and information from the following tables that have been provided in previous fiscal years: Tables 3A, 3B, 4A, 4B, 4C, 4D, and 4F. We are providing the data previously published as Table 4E for each annual proposed and final rule as one of our data files on the CMS Web page.

As discussed in sections II.G.3.e., II.G.10.a., II.G.11., and II.G.13. of the preamble of this final rule, we developed the following ICD–10–CM and ICD–10–PCS code tables for FY 2016: Table 6B—New Procedure Codes; Table 6I—Complete MCC List; Table 6J—Complete CC List; Table 6K—Complete List of CC Exclusions; Table 6L—Principal Diagnosis Is Its Own MCC List; Table 6M—Principal Diagnosis Is Its Own CC List; Table 6M.1—Additions to the Principal Diagnosis Is Its Own CC List; and Table 6P—ICD–10–PCS Code Translations for MS–DRG Changes. Table 6P contains multiple tables 6P.1a through 6P.2a that list the ICD–10–PCS code translations relating to specific 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.G. of the preamble of this final rule, we are not providing the hospital-level data as a table associated with this final rule. The hospital-level data for the FY 2016 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

Finally, a hospital's Factor 3 is the proportion of the uncompensated care amount that a DSH eligible hospital will receive under section 3133 of the Affordable Care Act. Factor 3 is the hospital's estimated number of Medicaid days and Medicare SSI days relative to the estimate of all DSH hospitals' Medicaid days and Medicare SSI days. Table 18 associated with this final rule contains the FY 2016 Medicare DSH uncompensated care payment Factor 3 for all hospitals and identifies whether or not a hospital is projected to receive DSH and, therefore, eligible to receive the additional payment for uncompensated care for FY 2016.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified below should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this FY 2016 final rule are available only through the Internet on the CMS Web site 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 2016 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download''.

Table 2—Case-Mix Index and Wage Index Table by CCN—FY 2016
Table 3—Wage Index Table by CBSA—FY 2016
Table 5—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2016.
Table 6B—New Procedure Codes—FY 2016
Table 6I— Complete Major CC List—FY 2016
Table 6J—Complete CC List—FY 2016
Table 6K—Complete List of CC Exclusions—FY 2016
Table 6L—Principal Diagnosis Is Its Own MCC List—FY 2016
Table 6M—Principal Diagnosis Is Its Own CC List—FY 2016
Table 6M1—Additions to the Principal Diagnosis Is Its Own CC List—FY 2016
Table 6P—ICD–10–PCS Code Translations for MS–DRG Changes—FY 2016
Table 7A—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2014 MedPAR Update—March 2015 GROUPER V32.0 MS–DRGs
Table 7B—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2014 MedPAR Update—March 2015 GROUPER V33.0 MS–DRGs
Table 8A—FY 2016 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B—FY 2016 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 10—New Technology Add-On Payment Thresholds for Applications for FY 2017
Table 14—List of Hospitals with Fewer Than 1,600 Medicare Discharges Based on the March 2015 Update of the FY 2014 MedPAR File and Potentially Eligible Hospitals for the FY 2016 Low-Volume Hospital Payment Adjustment (Eligibility for the low-volume hospital payment adjustment is also dependent upon meeting the mileage criteria specified at 42 CFR 412.101(b)(2)(ii))
Table 15—FY 2016 Readmissions Adjustment Factors
Table 16A—Updated Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2016
Table 18—FY 2016 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2016 final rule are available only through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1632–F:

Table 8C—FY 2016 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, Short-Stay Outlier (SSO) Threshold, and ''IPPS Comparable Threshold'' for LTCH PPS Discharges Occurring from October 1, 2015 through September 30, 2016
Table 12A—LTCH PPS Wage Index for Urban Areas for Discharges Occurring From October 1, 2015 through September 30, 2016
Table 12B—LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2015 through September 30, 2016
Table 13A—Composition of Low-Volume Quintiles for MS–LTC–DRGs—FY 2016
Table 13B—No-Volume MS-LTC-DRG Crosswalk for FY 2016

TABLE 1A—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (69.6 PERCENT LABOR SHARE/30.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2016

Hospital submitted quality data and is a meaningful EHR User (update = 1.7 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.1 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = 0.5 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −0.1 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,804.40	$1,466.69	$3,781.96	$1,651.89	$3,759.51	$1,642.08	$3,737.07	$1,632.28

TABLE 1B—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 2016

Hospital submitted quality data and is a meaningful EHR User (update = 1.7 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.1 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = 0.5 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −0.1 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,388.98	$2,077.11	$3,368.99	$2,064.86	$3,348.99	$2,052.60	$3,329.00	$2,040.35

TABLE 1C—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1; PUERTO RICO: 63.2 PERCENT LABOR SHARE/36.8 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1 OR 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1—FY 2016

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]	(*)	(*)	$3,388.98	$2,077.11
Puerto Rico	$1,648.66	$959.98	1,617.36	991.28

[1] For FY 2016, there are no CBSAs in Puerto Rico with a national wage index greater than 1.
* Not Applicable.

TABLE 1D—CAPITAL STANDARD FEDERAL PAYMENT RATES—FY 2016

	Rate
National	$438.65
Puerto Rico	212.56

TABLE 1E—LTCH PPS STANDARD FEDERAL RATE—FY 2016

	Full update (1.7 percent)	Reduced update * (−0.3 percent)
Standard Federal Rate	$41,762.85	$40,941.55

* For LTCHs that fail to submit quality reporting data for FY 2016 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. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this final rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the final changes for FY 2016 acute care hospital operating and capital payments will 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 payment changes in this final rule, will result in an estimated $378 million increase in FY 2016 operating payments (or 0.4 percent change) and an estimated $187 million increase in FY 2016 capital payments (or 2.3 percent change). These changes are

relative to payments made in FY 2015. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience a decrease in payments by $250 million in FY 2016 relative to FY 2015.

Our operating impact estimate includes the −0.8 percent documentation and coding adjustment applied to the IPPS standardized amount, which represents part of the recoupment required under section 631 of the ATRA. In addition, our operating payment impact estimate includes the 1.7 percent hospital update to the standardized amount (which includes the estimated 2.4 percent market basket update less 0.5 percentage point for the multifactor productivity adjustment and less 0.2 percentage point required under the Affordable Care Act). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final 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 final rule will 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 final rule.

B. Statement of Need

This final 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 final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS payment system.

C. Objectives of the IPPS

The primary objective of the IPPS 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 final rule will 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 changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2016, 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.

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 32 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 July 2015, there were 3,369 IPPS acute care hospitals included in our analysis. This represents approximately 56 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,334 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, 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 for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the update and policy changes to the LTCH PPS for FY 2016 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2015, 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, 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, 251 rehabilitation hospitals and 884 rehabilitation units, and approximately 429 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 495 psychiatric hospitals and 1,122 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated above, IRFs and IPFs are not affected by the rate updates discussed in this rule. The impacts of the 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, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2016 percentage increase in the 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. As discussed in section IV. of the preamble of the FY 2014 IPPS/LTCH PPS final rule, we rebased the IPPS operating market basket to a FY 2010 base year. Therefore, we are using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2016 and subsequent fiscal years 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, and RNHCIs that are paid based on reasonable costs subject to the rate-of-increase limits. Consistent with current law, based on IHS Global Insight, Inc.'s second quarter 2015 forecast of the FY 2010-based market basket increase, we are estimating that the FY 2016 update based on the IPPS operating market basket is 2.4 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be 0.5 percentage point for FY 2016) and a 0.2 percentage point reduction to the market basket update resulting in a 1.7 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.A. of the preamble of this final 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, and RNCHIs 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 update is the percentage increase in the FY 2016 IPPS operating market basket, estimated at 2.4 percent, without the reductions described above under the Affordable Care Act.

The impact of the 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 will 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 Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing final policy changes and final payment rate updates for the IPPS for FY 2016 for operating costs of acute care hospitals. The FY 2016 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 total FY 2016 operating payments will increase by 0.4 percent compared to FY 2015. In addition to the applicable percentage increase, this amount reflects the FY 2016 recoupment adjustment for documentation and coding described in section II.D. of the preamble of this final rule of -0.8 percent to the IPPS national standardized amounts. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the changes to each system. This section deals with the 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 changes in this final rule. However, there are other changes for which we do not have data available that will allow us to estimate the payment impacts using this model. For those 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 changes in payments per case presented below are taken from the FY 2014 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the 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 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 2014 MedPAR file, we simulated payments under the operating IPPS given various combinations of payment parameters. As described above, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, or the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2016 are discussed in section I.I. of this Appendix.

We discuss the following changes below:

- The effects of the application of the documentation and coding adjustment and the applicable percentage increase (including the market basket update, the 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 changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2012, compared to the FY 2011 wage data, to calculate the FY 2016 wage index.
- The combined effects of the recalibration of the MS–DRG relative weights as required by section 1886(d)(4)(C) of the Act and the wage index (including the updated wage data and the continued implementation of the new OMB labor market area delineations), including the wage and recalibration budget neutrality factors.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this final rule) that will be effective for FY 2016.
- The effects of the rural floor and imputed floor with the application of the national budget neutrality factor to the wage index.
- The effects of the second year of the 3-year transition for urban hospitals that were located in an urban county that become rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations.
- The effects of the frontier State wage index adjustment under the statutory provision that requires that hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. This provision is not budget neutral.
- The total estimated change in payments based on the FY 2016 policies relative to payments based on FY 2015 policies that include the applicable percentage increase of 1.7 percent (or 2.4 percent market basket update with a reduction of 0.5 percentage point for the multifactor productivity adjustment, and a 0.2 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the FY 2016 changes, our analysis begins with a FY 2015 baseline simulation model using: The FY 2015 applicable percentage increase of 2.2 percent and the documentation and coding recoupment adjustment of −0.8 percent to the Federal standardized amount; the FY 2015 MS–DRG GROUPER (Version 32); the FY 2015 CBSA designations for hospitals based on the new OMB definitions; the FY 2015 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2016, we are establishing 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 will receive an applicable percentage increase of 1.1 percent. At the time that this impact was prepared, 26 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2015 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the payment changes for FY 2016 using a reduced update for these 26 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2016.

For FY 2016, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not an meaningful EHR user will be subject to a reduction of one-half of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, for FY 2016, we are establishing 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 will receive an applicable percentage increase of 0.5 percent. At the time that this impact analysis was prepared, 153 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2015 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 below, we modeled the payment changes for FY 2016 using a reduced update for these 153 hospitals. We did not include these hospitals in the model for estimation

purposes for FY 2015 because that was the first year hospitals experienced a reduction to their applicable percentage increase due to whether they are meaningful EHR users and data were not available at that time. However, we believe it is appropriate to include these 153 hospitals for estimation purposes in FY 2016 because FY 2016 will be the second year in which hospitals will experience this reduction and data on the prior year's performance are now available. For purposes of the simulations shown below, we modeled the payment changes for FY 2016 using a reduced update for these 153 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update increase for FY 2016.

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 will receive an applicable percentage increase of −0.1 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a one-half reduction of the market basket update for being identified as not a meaningful EHR user. At the time that this impact was prepared, 24 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2016 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. We did not include these hospitals in the model for estimation purposes for FY 2015 because that was the first year hospitals experienced a reduction to their applicable percentage increase due to whether they are meaningful EHR users and data were not available at that time. However, we believe it is appropriate to include these 24 hospitals for estimation purposes in FY 2016 because FY 2016 will be the second year in which hospitals will experience this reduction and data on the prior year's performance are now available. For purposes of the simulations shown below, we modeled the payment changes for FY 2016 using a reduced update for these 24 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update increase for FY 2016.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2016 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our final comparison illustrates the percent change in payments per case from FY 2015 to FY 2016. Three factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2016 using an applicable percentage increase of 1.7 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.4 percent with a reduction of 0.5 percentage point for the multifactor productivity adjustment and a 0.2 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 will receive an update of 1.1 percent. This 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 will receive an update of 0.5 percent, which includes a reduction of one-half of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users will receive an update of −0.1 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs also are equal to the applicable percentage increase, or 1.7 percent if the hospital submits quality data and is a meaningful EHR user. In addition, we are updating the Puerto Rico-specific amount by an applicable percentage increase of 1.7 percent.

A second significant factor that affects the changes in hospitals' payments per case from FY 2015 to FY 2016 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 2015 that are no longer reclassified in FY 2016. Conversely, payments may increase for hospitals not reclassified in FY 2015 that are reclassified in FY 2016.

A third significant factor is that we currently estimate that actual outlier payments during FY 2015 will be 4.6 percent of total MS–DRG payments. When the FY 2015 IPPS/LTCH PPS final rule was published, we projected FY 2015 outlier payments would be 5.1 percent of total MS–DRG plus outlier payments; the average standardized amounts were offset correspondingly. The effects of the lower than expected outlier payments during FY 2015 (as discussed in the Addendum to this final rule) are reflected in the analyses below comparing our current estimates of FY 2015 payments per case to estimated FY 2016 payments per case (with outlier payments projected to equal 5.1 percent of total MS–DRG payments).

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2016. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,369 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 2,533 hospitals located in urban areas included in our analysis. Among these, there are 1,393 hospitals located in large urban areas (populations over 1 million), and 1,140 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 836 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final 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 2016 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 2,476; 1,386; 1,090; and 893, respectively.

The next three groupings examine the impacts of the 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 2,326 nonteaching hospitals in our analysis, 794 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 changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 189 RRCs, 327 SCHs, 150 MDHs, 126 hospitals that are both SCHs and RRCs, and 13 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 2013 or FY 2012 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 2016. The second grouping shows the MGCRB rural reclassifications. The final category shows the impact of the policy changes on the 14 cardiac hospitals.

TABLE I—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2016

	Number of hospitals [1]	Hospital rate update and documentation and coding adjustment (1) [2]	FY 2016 weights and DRG changes with application of recalibration budget neutrality (2) [3]	FY 2016 wage data under new CBSA designations with application of wage budget neutrality (3) [4]	FY 2016 DRG, rel. wts., wage index changes with wage and recalibration budget neutrality (4) [5]	FY 2016 MGCRB reclassifications (5) [6]	Rural and imputed floor with application of national rural and imputed floor budget neutrality (6) [7]	Application of the frontier wage index and out-migration adjustment (7) [8]	All FY 2016 changes (8) [9]
All Hospitals	3,369	0.9	0	0	0	0	0	0.1	0.4
By Geographic Location:									
Urban hospitals	2,533	0.9	0	0	0.1	−0.1	0	0.1	0.4
Large urban areas	1,393	0.9	0.1	0.1	0.2	−0.3	0	0.1	0.4
Other urban areas	1,140	0.9	0	−0.1	−0.2	0.1	0.1	0.2	0.4
Rural hospitals	836	1.3	−0.2	−0.3	−0.5	1.4	−0.2	0.1	0.2
Bed Size (Urban):									
0–99 beds	668	0.9	−0.3	−0.2	−0.4	−0.6	0.1	0.3	0.2
100–199 beds	778	0.9	−0.1	0.1	0.1	0	0.3	0.2	0.4
200–299 beds	445	0.9	0	0	0	0.1	0	0.1	0.4
300–499 beds	428	0.9	0	0	0	−0.2	0.1	0.2	0.4
500 or more beds	214	0.9	0.1	0.1	0.2	−0.2	−0.2	0.1	0.4
Bed Size (Rural):									
0–49 beds	329	1.3	−0.2	−0.3	−0.5	0.3	−0.2	0.3	−0.1
50–99 beds	297	1.4	−0.3	−0.2	−0.5	0.7	−0.2	0.1	0.2
100–149 beds	121	1.4	−0.2	−0.2	−0.5	1.7	−0.3	0.2	0.4
150–199 beds	48	1.2	−0.2	−0.4	−0.5	1.9	−0.3	0.1	0.3
200 or more beds	41	1.1	−0.1	−0.5	−0.5	2.5	−0.2	−0.1	0.1
Urban by Region:									
New England	120	0.9	0	0.7	0.7	1.3	1.6	0	−0.1
Middle Atlantic	318	0.9	0.1	0.2	0.3	0.8	−0.4	0.2	1
South Atlantic	407	0.9	0	0.1	0.1	−0.5	−0.4	0.1	0.2
East North Central	396	0.9	0	0	0.1	−0.3	−0.5	0	0.5
East South Central	150	0.9	0	−0.4	−0.4	−0.7	−0.4	0	−0.4
West North Central	166	0.9	0	−0.6	−0.5	−0.8	−0.4	0.8	0.3
West South Central	384	0.9	0	−0.5	−0.4	−0.6	−0.5	0	−0.4
Mountain	161	1	−0.1	−0.3	−0.3	0	−0.1	0.2	0.2
Pacific	380	0.9	0	0.4	0.3	−0.3	1.7	0.1	1
Puerto Rico	51	1	0.1	−0.9	−0.7	−1	0.1	0.1	−2.4
Rural by Region:									
New England	22	1.2	−0.1	−0.6	−0.7	1.7	−0.4	0	−0.1
Middle Atlantic	55	1.4	−0.1	0.2	0	0.8	−0.2	0.2	0.2
South Atlantic	128	1.2	−0.2	−0.1	−0.3	2.4	−0.2	0	0.6
East North Central	116	1.4	−0.2	−0.1	−0.4	1	−0.2	0.1	0.9
East South Central	164	0.9	0	−0.7	−0.7	2.5	−0.4	0.1	−1
West North Central	101	1.7	−0.4	−0.2	−0.5	0.2	0	0.3	0.8
West South Central	165	1.2	−0.1	−0.9	−0.9	1.5	−0.3	0.1	−0.8
Mountain	61	1.4	−0.3	−0.1	−0.4	0.2	−0.1	0.2	0.7
Pacific	24	1.4	−0.4	0.1	−0.3	0.6	−0.2	0	1.5
By Payment Classification:									
Urban hospitals	2,476	0.9	0	0	0.1	−0.1	0	0.1	0.4
Large urban areas	1,386	0.9	0.1	0.1	0.2	−0.3	0	0.1	0.4
Other urban areas	1,090	0.9	0	−0.1	−0.1	0.1	0.1	0.2	0.4
Rural areas	893	1.3	−0.2	−0.3	−0.4	1.1	−0.2	0.3	0.3
Teaching Status:									

TABLE I—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2016—Continued

	Number of hospitals [1]	Hospital rate update and documentation and coding adjustment (1) [2]	FY 2016 weights and DRG changes with application of recalibration budget neutrality (2) [3]	FY 2016 wage data under new CBSA designations with application of wage budget neutrality (3) [4]	FY 2016 DRG, rel. wts., wage index changes with wage and recalibration budget neutrality (4) [5]	FY 2016 MGCRB reclassifications (5) [6]	Rural and imputed floor with application of national rural and imputed floor budget neutrality (6) [7]	Application of the frontier wage index and out-migration adjustment (7) [8]	All FY 2016 changes (8) [9]
Nonteaching	2,326	1	−0.1	−0.1	−0.1	0.1	0.2	0.1	0.3
Fewer than 100 residents	794	0.9	0	−0.1	−0.1	−0.1	0	0.2	0.4
100 or more residents	249	0.9	0.2	0.1	0.3	0	−0.2	0.1	0.4
Urban DSH:									
Non-DSH	653	0.9	−0.2	0.1	−0.1	0.1	−0.1	0.1	1.1
100 or more beds	1,593	0.9	0.1	0	0.1	−0.1	0	0.1	0.3
Less than 100 beds	328	0.9	−0.1	0	−0.1	−0.7	0	0.3	0.2
Rural DSH:									
SCH	260	1.6	−0.3	0	−0.4	0	0	0	0.7
RRC	347	1.3	−0.2	−0.3	−0.4	1.5	−0.2	0.4	0.4
100 or more beds	31	0.7	0.1	−0.6	−0.5	2.4	−0.5	0.1	−0.9
Less than 100 beds	157	0.8	0	−0.7	−0.6	1.7	−0.5	0.6	−1.2
Urban teaching and DSH:									
Both teaching and DSH	855	0.9	0.1	0	0.1	−0.2	−0.1	0.1	0.3
Teaching and no DSH	122	0.9	−0.1	0	−0.1	0.8	0.1	0.1	1.3
No teaching and DSH	1,066	0.9	0	0	−0.1	−0.1	0.4	0.1	0.2
No teaching and no DSH	433	0.9	−0.2	0.1	−0.1	−0.4	−0.2	0.1	1
Special Hospital Types:									
RRC	189	0.9	−0.1	−0.6	−0.6	2.1	−0.3	0.6	−0.4
SCH	327	1.6	−0.3	−0.1	−0.3	−0.1	−0.1	0	0.8
MDH	150	1.3	−0.3	−0.2	−0.4	0.2	−0.2	0.2	0.6
SCH and RRC	126	1.6	−0.3	−0.1	−0.4	0.4	0	0	0.9
MDH and RRC	13	1.5	−0.3	0	−0.4	0.1	−0.2	0	0.6
Type of Ownership:									
Voluntary	1,934	0.9	0	0	0	0	0	0.1	0.5
Proprietary	879	0.9	0	−0.1	−0.1	0	0.1	0.1	−0.1
Government	529	0.9	0.1	−0.1	0	−0.2	0.1	0.1	0
Medicare Utilization as a Percent of Inpatient Days:									
0–25	533	0.9	0.1	−0.1	0	−0.4	0.2	0	−0.6
25–50	2,134	0.9	0	0	0	0	0	0.1	0.5
50–65	571	1	−0.1	0.1	0	0.6	0	0.1	0.8
Over 65	97	1.1	−0.1	−0.2	−0.4	−0.4	0.3	0.1	0.4
FY 2016 Reclassifications by the Medicare Geographic Classification Review Board:									
All Reclassified Hospitals	830	1	0	−0.1	−0.1	2.2	0.1	0	0.7
Non-Reclassified Hospitals	2,539	0.9	0	0	0.1	−0.9	0	0.2	0.2
Urban Hospitals Reclassified	551	0.9	0	−0.1	0	2.2	0.1	0	0.8
Urban Nonreclassified Hospitals	1,925	0.9	0	0.1	0.1	−0.9	0	0.1	0.2
Rural Hospitals Reclassified Full Year	279	1.2	−0.2	−0.3	−0.5	2.3	−0.2	0	0.4
Rural Nonreclassified Hospitals Full Year	504	1.4	−0.3	−0.3	−0.5	−0.3	−0.2	0.3	0
All Section 401 Reclassified Hospitals:	64	1.4	−0.3	0	−0.2	−0.4	0	1.4	0.6
Other Reclassified Hospitals (Section 1886(d)(8)(B))	53	1	−0.1	−0.5	−0.6	3.4	−0.4	0	−0.3
Specialty Hospitals:									

Cardiac specialty Hospitals	14	0.9	0.2	−0.9	−0.6	−1.1	0	0.9	0.7

[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 2014, and hospital cost report data are from reporting periods beginning in FY 2013 and FY 2012.

[2] This column displays the payment impact of the hospital rate update and the documentation and coding adjustment including the 1.7 percent adjustment to the national standardized amount and hospital-specific rate (the estimated 2.4 percent market basket update reduced by the 0.5 percentage point for the multifactor productivity adjustment and the 0.2 percentage point reduction under the Affordable Care Act) and the −0.8 percent documentation and coding adjustment to the national standardized amount.

[3] This column displays the payment impact of the changes to the Version 33 GROUPER, the changes to the relative weights and the recalibration of the MS–DRG weights based on FY 2014 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.998399 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2012 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 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 wage budget neutrality factor is 0.998749.

[5] This column displays the combined payment impact of the changes in Columns 2 through 3 and the cumulative budget neutrality factor for MS–DRG and wage changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act. The cumulative wage and recalibration budget neutrality factor of 0.997150 is the product of the wage budget neutrality factor and the recalibration budget neutrality factor.

[6] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB) along with the effects of the continued implementation of the new OMB labor market area delineations on these reclassifications. The effects demonstrate the FY 2016 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2016. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.987905.

[7] This column displays the effects of the rural floor and imputed floor based on the continued implementation of the new OMB labor market area delineations. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The rural floor budget neutrality factor (which includes the imputed floor) applied to the wage index is 0.990298. This column also shows the effect of the 3-year transition for hospitals that were located in urban counties that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations, with a budget neutrality factor of 0.999996.

[8] 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 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. These are nonbudget neutral policies.

[9] This column shows the changes in payments from FY 2015 to FY 2016. It reflects the impact of the FY 2016 hospital update and the adjustment for documentation and coding. It also reflects changes in hospitals' reclassification status in FY 2016 compared to FY 2015. It incorporates all of the changes displayed in Columns 1, 4, 5, 6, and 7, (the changes displayed in Columns 2 and 3 are included in Column 4). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.

a. Effects of the Hospital Update and Documentation and Coding Adjustment (Column 1)

As discussed in section II.D. of the preamble of this final rule, this column includes the hospital update, including the 2.4 percent market basket update, the reduction of 0.5 percentage point for the multifactor productivity adjustment, and the 0.2 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the FY 2016 documentation and coding recoupment adjustment of −0.8 percent on the national standardized amount as part of the recoupment required by section 631 of the ATRA. As a result, we are making a 0.9 percent update to the national standardized amount. This column also includes the 1.7 percent update to the hospital-specific rates which includes the 2.4 percent market basket update, the reduction of 0.5 percentage point for the multifactor productivity adjustment, and the 0.2 percentage point reduction in accordance with the Affordable Care Act.

Overall, hospitals will experience a 0.9 percent increase in payments primarily due to the combined effects of the hospital update and the documentation and coding adjustment on the national standardized amount and the hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate, namely SCHs, will experience a 1.6 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate will experience increases in payments of more than 0.9 percent.

b. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights with Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the changes to the MS–DRGs and relative weights with the application of the 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 are calculating a 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 final rule, the FY 2016 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2016, the MS–DRGs are calculated using the FY 2014 MedPAR data grouped to the Version 33 (FY 2016) MS–DRGs. The methodology to calculate the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.H. of the preamble of this final rule.

The ''All Hospitals'' line in Column 2 indicates that changes due to the MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 0.998399 on to the standardized amount. Hospital categories that generally treat more surgical cases than medical cases will experience increases in their payments under the relative weights. Rural hospitals will experience a 0.2 percent decrease in payments because rural hospitals tend to treat fewer surgical cases than medical cases, while teaching hospitals with more than 100 residents will experience an increase in payments by 0.2 percent as those hospitals treat more surgical cases than medical cases.

c. Effects of the Wage Index Changes (Column 3)

Column 3 shows the impact of updated wage data using FY 2012 cost report data, with the application of the 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 2016 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). (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).

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 wage index for acute care hospitals for FY 2016 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2011 and before October 1, 2012. The estimated impact of the updated wage data using the FY 2012 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2015 wage index, based on FY 2011 wage data, the labor-related share of 69.6 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2016 pre-reclassification wage index based on FY 2012 wage data with the labor-related share of 69.6 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 33 MS–DRG GROUPER constant. The FY 2016 occupational mix adjustment is based on the CY 2013 occupational mix survey.

In addition, the column shows the impact of the application of the 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 2016, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 69.6 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 FY 2016 wage budget neutrality factor is 0.998749, and the overall payment change is 0.0 percent.

Column 3 shows the impacts of updating the wage data using FY 2012 cost reports. Overall, the new wage data and the labor-related share, combined with the wage budget neutrality adjustment, will lead to no change for all hospitals as shown in Column 3.

In looking at the wage data itself, the national average hourly wage increased 1.03 percent compared to FY 2015. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 1.03 percent increase in average hourly wage. Of the 3,328 hospitals with wage data for both FYs 2015 and 2016, 1.594 or 47.9 percent will experience an average hourly wage increase of 1.03 percent or more.

The following chart compares the shifts in wage index values for hospitals due to changes in the average hourly wage data for FY 2016 relative to FY 2015. Among urban hospitals, 5 will experience a decrease of 10 percent or more, and 13 urban hospitals will experience an increase of 10 percent or more. One hundred and forty-four urban hospitals will experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, 9 will experience a decrease of at least 5 percent but less than 10 percent, but no rural hospitals will experience an increase of greater than or equal to 5 percent but less than 10 percent. No rural hospital will experience increases or decreases of 10 percent or more. However, 809 rural hospitals will experience increases or decreases of less than 5 percent, while 2,341 urban hospitals will experience increases or decreases of less than 5 percent. Seven urban hospitals will not experience a change in their wage index, and all rural hospitals will experience a change in their wage indexes. These figures reflect changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural and imputed floors, the out-migration adjustment, and other wage index exceptions and adjustments. (We refer readers to sections III.G.2. through III.I. of the preamble of this final rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this final rule, which are available via the Internet on the CMS Web site) is used to

adjust the labor-related share of a hospital's standardized amount, either 69.6 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 pre-reclassified wage index figures in the chart below may illustrate a somewhat larger or smaller change than will occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the area wage index values for urban and rural hospitals.

FY 2016 percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase 10 percent or more	13	0
Increase greater than or equal to 5 percent and less than 10 percent	64	0
Increase or decrease less than 5 percent	2,341	809
Decrease greater than or equal to 5 percent and less than 10 percent	80	9
Decrease 10 percent or more	5	0
Unchanged	7	0

d. Combined Effects of the MS–DRG and Wage Index Changes (Column 4)

Section 1886(d)(4)(C)(iii) of the Act requires that changes to MS–DRG reclassifications and the relative weights cannot increase or decrease aggregate payments. In addition, section 1886(d)(3)(E) of the Act specifies that any updates or adjustments to the wage index are to be budget neutral. We computed a wage budget neutrality factor of 0.998749 and a recalibration budget neutrality factor of 0.998399 (which is also applied to the Puerto Rico-specific standardized amount and the hospital-specific rates). The product of the two budget neutrality factors is the cumulative wage and recalibration budget neutrality factor. The cumulative wage and recalibration budget neutrality adjustment is 0.997150, or approximately 0.3 percent, which is applied to the national standardized amounts. Because the wage budget neutrality and the recalibration budget neutrality are calculated under different methodologies according to the statute, when the two budget neutralities are combined and applied to the standardized amount, the overall payment impact is not necessarily budget neutral. However, in this final rule, we are estimating that the changes in the MS–DRG relative weights and updated wage data with wage and budget neutrality applied will result in a 0.0 percent change in payments.

e. Effects of MGCRB Reclassifications (Column 5)

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 changes in Column 5 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2016.

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 publication of the IPPS proposed rule in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

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 applying an adjustment of 0.987905 to ensure that the effects of the reclassifications under section 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this final rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification will increase payments to rural hospitals by an average of 1.4 percent. By region, all the rural hospital categories will experience increases in payments due to MGCRB reclassifications.

New Table 2 listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site reflects the reclassifications for FY 2016.

f. Effects of the Rural and Imputed Floor, Including Application of National Budget Neutrality (Column 6)

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, 2012, 2013, 2014, and 2015 IPPS/LTCH PPS final rules, and this final 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 apply a uniform budget neutrality adjustment to the wage index. The imputed floor, which is also included in the calculation of the budget neutrality adjustment to the wage index, was extended in FY 2012 for 2 additional years and in FY 2014 and FY 2015 for 1 additional year. Prior to FY 2013, only urban hospitals in New Jersey received the imputed floor. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53369), we established an alternative temporary methodology for the imputed floor, which resulted in an imputed floor for Rhode Island for FY 2013. For FY 2014 and FY 2015, we extended the imputed rural floor, as calculated under the original methodology and the alternative methodology. Due to the adoption of the new OMB labor market area delineations in FY 2015, the State of Delaware also became an all-urban state and thus eligible for an imputed floor. For FY 2016, we are extending the imputed rural floor for 1 year, as calculated under the original methodology and the alternative methodology. As a result, New Jersey, Rhode Island, and Delaware are able to receive an imputed floor. In New Jersey, 21 out of 64 hospitals will receive the imputed floor, and 4 out of 11 hospitals in Rhode Island will receive the imputed floor for FY 2016. For FY 2016, no hospitals will benefit from the imputed floor in Delaware because the CBSA wage index for each CBSA in Delaware under the new OMB delineations is equal to or higher than the imputed rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally, and the imputed floor is part of the rural floor budget neutrality factor applied to the wage index nationally. We have calculated a FY 2016 rural floor budget neutrality factor to be applied to the wage index of 0.990298, which will reduce wage indexes by 0.99 percent.

Column 6 shows the projected impact of the rural floor and imputed 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 post-reclassification FY 2016 wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2016 wage index of providers with the rural floor and imputed floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural and imputed 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) will experience a decrease in payments due to the budget neutrality adjustment that is applied nationally to their wage index.

We estimate that 371 hospitals will benefit from the rural and imputed floors in FY 2016, while the remaining 2,998 IPPS hospitals in our model will have their wage index reduced by the rural floor budget neutrality adjustment of 0.990298 (or 0.99 percent). We project that, in aggregate, rural hospitals will experience a 0.2 percent decrease in payments as a result of the application of the 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 will experience no change in payments because 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 will experience a 1.6 percent increase in payments primarily due to the application of the rural floor in Massachusetts. Thirty-nine urban providers in Massachusetts are expected to receive the rural floor wage index value, including the rural floor budget neutrality of 0.990298, increasing payments overall to Massachusetts by an estimated $98 million. We estimate that Massachusetts hospitals will receive approximately a 3.1 percent increase in IPPS payments due to the application of the rural floor in FY 2016.

Urban Puerto Rico hospitals are expected to experience a 0.1 percent change in payments as a result of the application of the Puerto Rico rural floor with the application of the Puerto Rico rural floor budget neutrality adjustment. We are applying a rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.987646 or 1.2 percent. The Puerto Rico-specific wage index adjusts the Puerto Rico-specific standardized amount, which represents 25 percent of payments to Puerto Rico hospitals. The increases in payments experienced by the urban Puerto Rico hospitals that benefit from a rural floor are offset by the decreases in payments by the urban Puerto Rico hospitals that do not benefit from the rural floor that have their wage indexes downwardly adjusted by the rural floor budget neutrality adjustment. As a result, overall, urban Puerto Rico hospitals will experience a 0.1 percent change in payments due to the application of the rural floor with rural floor budget neutrality.

There are 21 hospitals out of the 64 hospitals in New Jersey that will benefit from the extension of the imputed floor and will receive the imputed floor wage index value under the OMB labor market area delineations, including the rural floor budget neutrality of 0.990298 which we estimate will increase payments to those imputed floor hospitals by $27 million (overall, the State will receive an increase of $9 million in payments due to the other hospitals in the State that will experience decreases in payments due to the rural floor budget neutrality adjustment). Four Rhode Island hospitals will benefit from the imputed rural floor calculated under the alternative methodology and will receive an additional $4.5 million (overall, the State will receive an additional $2.6 million). While some hospitals in Delaware are geographically located in CBSAs that are assigned the imputed floor, none of these hospitals benefit from the imputed floor since they are reclassifying to CBSAs with a higher wage index than the imputed floor.

Column 6 also shows the projected effects of the second year of the 3-year hold harmless provision for hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations. As discussed in section III.G.2. of the preamble of this final rule, under this transition, hospitals that were located in an urban county that became rural under the new OMB delineations will generally be assigned the urban wage index value of the CBSA in which they are physically located in FY 2014 for a period of 3 fiscal years (that is, FYs 2015, 2016, and 2017). In addition, as discussed in section III.G.3. of the preamble of this final rule, under this transition, hospitals that were deemed urban where the urban area became rural under the new OMB delineations will generally be assigned the area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index, if applicable) to which they were designated in FY 2014. For FY 2016, we are applying the 3-year transition wage index adjustments in a budget neutral manner, with a budget neutrality factor of 0.999996.

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 and imputed floor with budget neutrality at the State level. Column 1 of the table below displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that will receive the rural floor or imputed floor wage index for FY 2016. Column 3 displays the percentage of total payments each State will receive or contribute to fund the rural floor and imputed floor with national budget neutrality. The column compares the post-reclassification FY 2016 wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2016 wage index of providers with the rural floor and imputed floor adjustment. Column 4 displays the estimated payment amount that each State will gain or lose due to the application of the rural floor and imputed floor with national budget neutrality.

FY 2016 IPPS Estimated Payments Due to Rural Floor and Imputed Floor With National Budget Neutrality

State	Number of hospitals (1)	Number of hospitals that will receive the rural floor or imputed floor (2)	Percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Difference (in millions) (4)
Alabama	86	3	−0.4	$−6.72
Alaska	6	1	−0.3	−0.51
Arizona	55	5	−0.3	−5.65
Arkansas	46	0	−0.4	−.43
California	303	203	2.2	220.65
Colorado	47	5	0.4	4.51
Connecticut	31	7	−0.5	−8.06
Delaware	6	0	-0.5	−2.41
Washington, DC	7	0	−0.5	−2.37
Florida	170	14	−0.3	−18.34
Georgia	105	0	−0.5	−11.96
Hawaii	12	1	−0.4	−1.11
Idaho	14	0	−0.4	−1.15
Illinois	127	2	−0.5	−24.07
Indiana	91	0	−0.5	−11.65
Iowa	35	0	−0.4	−4.15
Kansas	53	0	−0.4	−3.5
Kentucky	65	1	−0.4	−6.76
Louisiana	99	3	−0.5	−6.39
Maine	20	0	−0.5	−2.22
Massachusetts	61	39	3.1	97.64
Michigan	96	0	−0.5	−21.43
Minnesota	50	0	−0.3	−5.99

FY 2016 IPPS ESTIMATED PAYMENTS DUE TO RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals (1)	Number of hospitals that will receive the rural floor or imputed floor (2)	Percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Difference (in millions) (4)
Mississippi	64	0	−0.5	−4.75
Missouri	78	0	−0.4	−9.54
Montana	12	2	0.1	0.19
Nebraska	26	0	−0.4	−2.43
Nevada	24	3	0.2	1.8
New Hampshire	13	3	−0.1	−0.53
New Jersey	64	21	0.2	8.95
New Mexico	25	0	−0.3	−1.35
New York	156	2	−0.6	−43.23
North Carolina	84	0	−0.4	−13.95
North Dakota	6	0	−0.3	−0.8
Ohio	132	6	−0.4	−16.71
Oklahoma	86	4	−0.3	−4.21
Oregon	34	0	−0.5	−4.65
Pennsylvania	153	3	−0.5	−21.99
Puerto Rico	51	10	0.1	0.17
Rhode Island	11	4	0.7	2.57
South Carolina	56	5	−0.2	−2.73
South Dakota	19	0	−0.3	−0.97
Tennessee	99	10	−0.4	−9.69
Texas	318	3	−0.5	−29.15
Utah	34	2	−0.4	−1.91
Vermont	6	0	−0.3	−0.57
Virginia	78	1	−0.4	−11.13
Washington	49	6	0.1	1.47
West Virginia	29	2	0.1	1.04
Wisconsin	66	0	−0.5	−7.85
Wyoming	11	0	−0.2	−0.22

g. Effects of the Application of the Frontier State Wage Index and Out-Migration Adjustment (Column 7)

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 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, 4 States (Montana, North Dakota, South Dakota, and Wyoming) are considered frontier States and 48 hospitals located in those States will receive a frontier wage index of 1.0000. Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, but since then and including in this final rule, its rural floor value has been greater than 1.0000 so it has not been subject to the frontier wage index. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $60 million. Rural and urban hospitals located in the West North Central region will experience an increase in payments by 0.3 and 0.8 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 are to 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 336 providers that will receive the out-migration wage adjustment in FY 2016. Rural hospitals generally 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 will experience a 1.4 percent and 0.6 percent increase in payments, respectively. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase will be approximately $45 million.

h. Effects of All FY 2016 Changes (Column 8)

Column 8 shows our estimate of the changes in payments per discharge from FY 2015 and FY 2016, resulting from all changes reflected in this final rule for FY 2016. It includes combined effects of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 0.4 percent for FY 2016 relative to FY 2015. As discussed in section II.D. of the preamble of this final rule, this column includes the FY 2016 documentation and coding recoupment adjustment of −0.8 percent on the national standardized amount as part of the recoupment required under section 631 of the ATRA. In addition, this column includes the annual hospital update of 1.7 percent to the national standardized amount. This annual hospital update includes the 2.4 percent market basket update, the reduction of 0.5 percentage point for the multifactor productivity adjustment, and the 0.2 percentage point reduction under section

3401 of the Affordable Care Act. Hospitals paid under the hospital-specific rate will receive a 1.7 percent hospital update described above. As described in Column 1, the annual hospital update with the documentation and coding recoupment adjustment for hospitals paid under the national standardized amount combined with the annual hospital update for hospitals paid under the hospital-specific rate will result in a 0.9 percent increase in payments in FY 2016 relative to FY 2015. The impact of moving from our estimate of FY 2015 outlier payments, 4.6 percent, to the estimate of FY 2016 outlier payments, 5.1 percent, will result in an increase of 0.4 percent in FY 2016 payments relative to FY 2015. There also might be interactive effects among the various factors comprising the payment system that we are not able to isolate. For these reasons, the values in Column 8 may not equal the sum of the estimated percentage changes described above.

Overall payments to hospitals paid under the IPPS due to the applicable percentage increase and changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 0.4 percent for FY 2016. Hospitals in urban areas will experience a 0.4 percent increase in payments per discharge in FY 2016 compared to FY 2015. Hospital payments per discharge in rural areas are estimated to increase by 0.2 percent in FY 2016.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2016 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 2015 with the estimated average payments per discharge for FY 2016, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the 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 8 of Table I.

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2016 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals	Estimated average FY 2015 payment per discharge	Estimated average FY 2016 payment per discharge	FY 2016 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,369	11,329	11,370	0.4
By Geographic Location:				
Urban hospitals	2,533	11,680	11,724	0.4
Large urban areas	1,393	12,434	12,482	0.4
Other urban areas	1,140	10,766	10,804	0.4
Rural hospitals	836	8,424	8,441	0.2
Bed Size (Urban):				
0–99 beds	668	9,254	9,273	0.2
100–199 beds	778	9,863	9,900	0.4
200–299 beds	445	10,589	10,633	0.4
300–499 beds	428	11,927	11,972	0.4
500 or more beds	214	14,285	14,340	0.4
Bed Size (Rural):				
0–49 beds	329	7,048	7,043	−0.1
50–99 beds	297	7,972	7,988	0.2
100–149 beds	121	8,290	8,325	0.4
150–199 beds	48	9,109	9,132	0.3
200 or more beds	41	9,996	10,004	0.1
Urban by Region:				
New England	120	12,850	12,836	−0.1
Middle Atlantic	318	13,156	13,282	1
South Atlantic	407	10,387	10,410	0.2
East North Central	396	10,950	11,009	0.5
East South Central	150	9,998	9,958	−0.4
West North Central	166	11,438	11,470	0.3
West South Central	384	10,590	10,548	−0.4
Mountain	161	12,013	12,036	0.2
Pacific	380	14,889	15,035	1
Puerto Rico	51	7,648	7,469	−2.4
Rural by Region:				
New England	22	11,441	11,429	−0.1
Middle Atlantic	55	8,545	8,565	0.2
South Atlantic	128	7,868	7,916	0.6
East North Central	116	8,775	8,852	0.9
East South Central	164	7,524	7,449	−1
West North Central	101	9,280	9,350	0.8
West South Central	165	7,218	7,160	−0.8
Mountain	61	9,730	9,796	0.7
Pacific	24	11,500	11,671	1.5
By Payment Classification:				
Urban hospitals	2,476	11,700	11,743	0.4
Large urban areas	1,386	12,440	12,488	0.4
Other urban areas	1,090	10,771	10,809	0.4
Rural areas	893	8,687	8,709	0.3
Teaching Status:				
Nonteaching	2,326	9,450	9,479	0.3
Fewer than 100 residents	794	10,999	11,041	0.4
100 or more residents	249	16,424	16,493	0.4

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2016 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2015 payment per discharge (2)	Estimated average FY 2016 payment per discharge (3)	FY 2016 changes (4)
Urban DSH:				
Non-DSH	653	9,946	10,052	1.1
100 or more beds	1,593	12,080	12,114	0.3
Less than 100 beds	328	8,526	8,546	0.2
Rural DSH:				
SCH	260	8,859	8,917	0.7
RRC	347	9,023	9,055	0.4
100 or more beds	31	7,544	7,479	−0.9
Less than 100 beds	157	6,774	6,696	−1.2
Urban teaching and DSH:				
Both teaching and DSH	855	13,217	13,261	0.3
Teaching and no DSH	122	11,161	11,300	1.3
No teaching and DSH	1,066	9,878	9,894	0.2
No teaching and no DSH	433	9,415	9,511	1
Special Hospital Types:				
RRC	189	9,449	9,408	−0.4
SCH	327	9,951	10,034	0.8
MDH	150	6,968	7,010	0.6
SCH and RRC	126	10,591	10,691	0.9
MDH and RRC	13	8,621	8,669	0.6
Type of Ownership:				
Voluntary	1,934	11,498	11,559	0.5
Proprietary	879	9,997	9,984	−0.1
Government	529	12,240	12,243	0
Medicare Utilization as a Percent of Inpatient Days:				
0–25	533	14,719	14,625	−0.6
25–50	2,134	11,265	11,321	0.5
50–65	571	9,180	9,249	0.8
Over 65	97	6,883	6,909	0.4
FY 2016 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	830	11,288	11,370	0.7
Non-Reclassified Hospitals	2,539	11,346	11,370	0.2
Urban Hospitals Reclassified	551	11,925	12,020	0.8
Urban Nonreclassified Hospitals	1,925	11,620	11,646	0.2
Rural Hospitals Reclassified Full Year	279	8,836	8,870	0.4
Rural Nonreclassified Hospitals Full Year	504	7,926	7,924	0
All Section 401 Reclassified Hospitals:	64	10,427	10,492	0.6
Other Reclassified Hospitals (Section 1886(d)(8)(B))	53	7,855	7,830	−0.3
Specialty Hospitals				
Cardiac specialty Hospitals	14	12,640	12,723	0.7

H. Effects of Other Policy Changes

In addition to those policy changes discussed above that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes. Our estimates of the likely impacts associated with these other changes are discussed below.

1. Effects of Policy on MS–DRGs for Preventable HACs, Including Infections

In section II.F. of the preamble of this final rule, we discuss our implementation of section 1886(d)(4)(D) of the Act, which requires the Secretary to identify conditions that are: (1) High cost, high volume, or both; (2) result in the assignment of a case to an MS–DRG that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission, unless, based on data and clinical judgment, it cannot be determined at the time of admission whether a condition is present. That is, the case will be paid as though the secondary diagnosis were not present. However, the statute also requires the Secretary to continue counting the condition as a secondary diagnosis that results in a higher IPPS payment when doing the budget neutrality calculations for MS–DRG reclassifications and recalibration. Therefore, we will perform our budget neutrality calculations as though the payment provision did not apply, but Medicare will make a lower payment to the hospital for the specific case that includes the secondary diagnosis. Thus, the provision results in cost savings to the Medicare program.

We note that the provision will only apply when one or more of the selected conditions are the only secondary diagnosis or diagnoses present on the claim that will lead to higher payment. Medicare beneficiaries will generally have multiple secondary diagnoses during a hospital stay, such that beneficiaries having one MCC or CC will frequently have additional conditions that also will generate higher payment. Only a small percentage of the cases will have only one secondary diagnosis that would lead to a higher payment. Therefore, if at least one nonselected secondary diagnosis that leads to higher payment is on the claim, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case. In addition, as discussed in section II.F.3. of the preamble of this final rule, it is possible to have two

severity levels where the HAC does not affect the MS–DRG assignment or for an MS–DRG not to have severity levels. In either of these circumstances, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case.

As discussed in section II.F. of the preamble of this final rule, for FY 2016, we are not adding or removing any categories of HACs for FY 2016.

The HAC payment provision went into effect on October 1, 2008. Our savings estimates for the next 5 fiscal years are shown below:

Year	Savings (in millions)
FY 2016	28
FY 2017	29
FY 2018	31
FY 2019	32
FY 2020	34

2. Effects of Policy Relating to New Medical Service and Technology Add-On Payments

In section II.I. of the preamble to this final rule, we discuss six applications (Blinatumomab (BLINCYTO™), DIAMONDBACK® 360 Coronary Orbital Atherectomy System, CRESEMBA® (Isavuconazonium), LUTONIX® Drug Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) and IN.PACT™Admiral™ Pacliaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter, VERASENSE™ Knee Balancer System (VKS), and WATCHMAN® Left Atrial Appendage Closure Technology) for add-on payments for new medical services and technologies for FY 2016, as well as the status of the new technologies that were approved to receive new technology add-on payments in FY 2015. We note that two of the applications (the Angel Medical Guardian® Ischemia Monitoring Device and Ceftazidime Avibactam (AVYCAZ)) discussed in the proposed rule withdrew their applications prior to the publication of this final rule. In addition, Idarucizumab did not receive FDA approval by July 1, 2015 in accordance with the regulations under § 412.87(c) and, therefore, is ineligible for consideration for new technology add-on payments for FY 2016.

As explained in the preamble to this final 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.I.4. of the preamble of this final rule, we are approving two of the six applications (BLINCYTO™ and LUTONIX® DCB PTA and IN.PACT™Admiral™ Pacliaxel Coated PTA Balloon Catheter) for new technology add-on payments for FY 2016. As we proposed, in this final rule, we also are continuing to make new technology add-on payments in FY 2016 for Kcentra™, Argus® II Retinal Prosthesis System, the CardioMEMS™ HF (Heart Failure) Monitoring System, MitraClip® System, and the Responsive Neurostimulator (RNS®) System (because all of these technologies are still within the 3-year anniversary of the product's entry onto the market). We note that new technology add-on payments per 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 add-on payments for FY 2016 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. Based on the applicant's estimate for FY 2014, we currently estimate that new technology add-on payments for Kcentra™ will increase overall FY 2016 payments by $5,449,888. Based on the applicant's estimate for FY 2014, we currently estimate that new technology add-on payments for the Argus® II Retinal Prosthesis System will increase overall FY 2016 payments by $3,601,437. Based on the applicant's estimate for FY 2015, we currently estimate that new technology add-on payments for the CardioMEMS™ HF Monitoring System will increase overall FY 2016 payments by $11,315,625. Based on the applicant's estimate for FY 2015, we currently estimate that new technology add-on payments for the MitraClip® System will increase overall FY 2016 payments by $27,000,000. Based on the applicant's estimate for FY 2015, we currently estimate that new technology add-on payments for the RNS® System will increase overall FY 2015 payments by $12,932,500. Based on the applicant's estimate for FY 2016, we currently estimate that new technology add-on payments for BLINCYTO™ will increase overall FY 2016 payments by $4,593,034 (maximum add-on payment of $27,017.85 * 170 patients). Based on the weighted cost average for FY 2016 described in section II.I.4. of the preamble to this final rule, we currently estimate that new technology add-on payments for LUTONIX® DCB PTA and IN.PACT™Admiral™ Pacliaxel Coated PTA Balloon Catheter will increase overall FY 2016 payments by $36,120,735 (maximum add-on payment of $1,035.72 * 8,875 patients for LUTONIX® DCB PTA Balloon Catheter; maximum add-on payment of $1,035.72 * 26,000 patients for IN.PACT™Admiral™ Pacliaxel Coated PTA Balloon Catheter).

3. Effects of the Changes to Medicare DSH Payments for FY 2016

As discussed in section IV.D. of the preamble of this final 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 former statutory formula for Medicare DSH payments. 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 individuals under age 65 who are uninsured 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 Medicare DSH hospital will receive an additional payment based on its estimated share of the total amount of uncompensated care for all Medicare DSH hospitals. The uncompensated care payment methodology has redistributive effects based on the proportion of a Medicare DSH hospital's low-income insured patient days (sum of Medicaid patient days and Medicare SSI patient days) relative to the low-income insured patient days for all Medicare DSH hospitals (Factor 3). The reduction to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this FY 2016 IPPS/LTCH PPS final rule, we are establishing the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2016 is $6,406,145,534.04, or 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 63.69 percent; for FY 2015, the amount available to be distributed for uncompensated care was $7,647,644,885.18, or 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 76.19 percent. To calculate Factor 3 for FY 2016, we are using Medicaid days from the more recent of hospitals' full year 2012 or full year 2011 cost reports from the March 2015 update of the HCRIS database (that is, we are holding constant the 2012 and 2011 cost report years used in the FY 2015 IPPS/LTCH PPS final rule, but using updated cost report data from a later extract of the HCRIS), Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the 2013 SSI ratios. This is in contrast to FY 2015, when we used Medicaid days from the hospitals' full year 2012 or 2011 cost reports from the March 2014 update of the HCRIS database, Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the 2012 SSI ratios to calculate Factor 3. The uncompensated care payment methodology is discussed in more detail in section IV.D. of the preamble of this final rule.

To estimate the impact of the combined effect of reductions in the percent of individuals under age 65 who are uninsured and additional statutory adjustments (Factor 2) and changes in Medicaid and SSI patient days (components of Factor 3) on the calculation of Medicare DSH payments, including both empirically justified Medicare DSH payments and uncompensated care payments, we compared total DSH payments estimated in the FY 2015 IPPS/LTCH PPS final rule and correction notice to total DSH payments estimated in this FY 2016 IPPS/LTCH PPS final rule. For FY 2015, for each hospital, we calculated the sum of (I) 25 percent of the estimated amount of what would have been paid as Medicare DSH in FY 2015 in the absence of section 3133 of the Affordable Care Act and (II) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments in the absence of section 3133, adjusted by a Factor 2 of 76.19 percent and multiplied by a Factor 3 as stated in the FY 2015 IPPS/LTCH PPS final rule and correction notice. For FY 2016, we calculated the sum of (I) 25 percent of the estimated amount of what would be paid as Medicare DSH payments in FY 2016 absent

section 3133 and (II) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments absent section 3133, adjusted by a Factor 2 of 63.69 percent and multiplied by a Factor 3 as stated above.

Our analysis included 2,418 hospitals that are projected to be eligible for DSH in FY 2016. It did not include hospitals in the Rural Community Hospital Demonstration, hospitals that departed the Medicare program as of July 7, 2015, Maryland hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. In addition, low-income insured days from merged or acquired hospitals were combined into the surviving hospital's CCN, and the nonsurviving CCN was excluded from the analysis. The estimated impact of changes in Factors 1, 2, and 3 across all FY 2016 DSH eligible hospitals, by hospital characteristic, is presented in the table below.

MODELED DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR ESTIMATED FY 2016 DSH HOSPITALS BY HOSPITAL TYPE: MODEL DSH $ (IN MILLIONS) FROM FY 2015 TO FY 2016

	Number of estimated FY 2016 DSH hospitals	FY 2015 estimated DSH $*	FY 2016 estimated DSH $*	Percentage change**
	(1)	(2)	(3)	(4)
Total	$2,418	$10,993	$9,733	−11.5
By Geographic Location:				
Urban Hospitals	1,892	10,453	9,260	−11.4
Large Urban Areas	1,024	6,629	5,858	−11.6
Other Urban Areas	868	3,823	3,402	−11.0
Rural Hospitals	526	540	473	−12.5
Bed Size (Urban):				
0–99 Beds	327	211	186	−11.8
100–249 Beds	827	2,514	2,196	−12.6
250–499 Beds	738	7,728	6,878	−11.0
Bed Size (Rural):				
0–99 Beds	392	235	206	−12.1
100–249 Beds	120	246	211	−14. 5
250–499 Beds	14	59	56	−5.6
Urban by Region:				
East North Central	308	1,421	1,268	−10.8
East South Central	131	649	575	-11.4
Middle Atlantic	231	1,804	1,603	−11.1
Mountain	115	504	447	−11.3
New England	86	440	388	−11.9
Pacific	298	1,649	1,454	−11.8
Puerto Rico	39	108	100	−8.1
South Atlantic	318	2,012	1,772	−11.9
West North Central	105	507	455	−10.1
West South Central	261	1,357	1,197	−11.8
Rural by Region:				
East North Central	67	55	49	−10.9
East South Central	147	174	149	−14.0
Middle Atlantic	27	40	34	−14.5
Mountain	22	18	16	−13.1
New England	10	17	15	−13.7
Pacific	10	6	8	35.3
South Atlantic	88	107	96	−9.5
West North Central	38	27	21	−20.1
West South Central	117	97	84	−13.6
By Payment Classification:				
Urban Hospitals	1,860	10,448	9,205	−11.9
Large Urban Areas	1,021	6,640	5,856	−11.8
Other Urban Areas	839	3,809	3,349	−12.1
Rural Hospitals	558	545	527	−3.2
Teaching Status:				
Nonteaching	1,548	3,578	3,106	−13.2
Fewer than 100 residents	630	3,585	3,194	−10.9
100 or more residents	240	3,831	3,432	−10.4
Type of Ownership:				
Voluntary	1,388	6,770	6,028	−11.0
Proprietary	541	1,904	1,661	−12.7
Government	487	2,290	2,017	−11.9
Unknown	2	30	27	−10.4

SOURCE: Dobson DaVanzo analysis of 2011–2012 Hospital Cost Reports, 2015 Provider of Services File, FY 2015 IPPS Final Rule CN Impact File, and FY 2016 NPRM Impact File.

* Dollar DSH calculated by [0.25 * estimated section 1886(d)(5)(F) payments] + [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, the Model DSH is $10,993 million in FY 2015 and $9,733 million in FY 2016.

** Percentage change is determined as the difference between Medicare DSH payments modeled for the FY 2016 IPPS/LTCH PPS final rule (column 3) and Medicare DSH payments modeled for the FY 2015 IPPS/LTCH final rule (column 2) divided by Medicare DSH payments modeled for the FY 2015 final rule (column 3) 1 times 100 percent.

The impact analysis found that changes from the FY 2015 IPPS/LTCH PPS final rule were primarily driven by three components: (1) A reduction in Factor 2 from 76.19 percent in the FY 2015 IPPS/LTCH PPS final rule to 63.69 percent in this FY 2016 IPPS/LTCH PPS final rule, (2) changes in the number of Medicaid days for 2012 (or 2011) obtained from the March 2014 HCRIS update of providers' Medicare cost report (used in the FY 2015 IPPS/LTCH PPS final rule) to the number of Medicaid days reported in the March 2015 HCRIS update of providers' Medicare cost report (used in this FY 2016 final rule); and (3) changes in SSI days from 2012 (used in the FY 2015 IPPS/LTCH PPS final rule and correction notice) to 2013 (used in this FY 2016 IPPS/LTCH PPS final rule). The change in the percentage of individuals who are uninsured is a national estimate affecting all hospitals equally, while the change in Medicaid days and SSI days is hospital-specific and drives the change in the Factor 3 computed for each hospital. Additionally, we note that several hospitals had a change in at least one of their payment or geographic characteristics from FY 2015 to FY 2016. Therefore, the number of hospitals within a given hospital characteristic may have changed from the FY 2015 final rule and correction notice. These changes also impact the distribution of Medicare DSH payments.

The impact analysis table above shows that across all DSH-eligible hospitals, FY 2016 DSH payments, including both empirically justified DSH payments and uncompensated care payments, are estimated at approximately $9.733 billion, or a decrease of approximately 11.5 percent from FY 2015 DSH payments ($10.993 billion). As a result, we project that payments for FY 2016 to hospitals paid under the IPPS will be reduced by 1.0 percent overall as compared to overall payments to hospitals paid under the IPPS in FY 2015.

Percent reductions greater than 11.5 percent in column 4 of the table above indicate that hospitals within the specified category are projected to experience a greater reduction in DSH payments, on average, relative to all of the FY 2016 DSH hospitals included in this analysis. Likewise, reductions less than 11.5 percent indicate that hospitals within each category, on average, are projected to receive a smaller reduction in DSH payments relative to all FY 2016 DSH hospitals. The variation in DSH payment reductions by hospital characteristic, as shown in column 4, is largely dependent on the change in a given hospital's number of SSI and Medicaid days, as well as variations in hospital characteristics or classification between FY 2015 and FY 2016 and the number of DSH-eligible hospitals. On average across all hospitals, the number of SSI days increased by 0.026 percent from FY 2015. On average across all hospitals, the number of Medicaid days increased by 0.621 percent from FY 2015. In conjunction with this FY 2016 IPPS/LTCH PPS final rule, we will publish an impact table as well as a supplemental data file that can be used to further analyze the distribution of DSH payments and variation in DSH payment reductions.

4. Effects of Reduction Under the Hospital Readmissions Reduction Program

In section IV.E. of the preamble of this final rule, we discuss our policies for FY 2016 for the Hospital Readmissions Reduction Program (established under section 3025 of the Affordable Care Act), which requires a reduction to a hospital's base operating DRG payments to account for excess readmissions. For FY 2016, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for five applicable conditions: acute myocardial infarction, heart failure, pneumonia, total hip and total knee arthroplasty and chronic obstructive pulmonary disease. This provision is not budget neutral. A hospital's readmission adjustment is the higher of a ratio of the hospital's aggregate payments for excess readmissions to their aggregate payments for all discharges, or a floor, which has been defined in the statute as 0.97 (or a 3.0 percent reduction). A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as discussed in section IV.E. of the preamble of this final rule) is the portion of the IPPS payment subject to the readmissions payment adjustment (DSH, IME, outliers and low-volume add-on payments are not subject to the readmissions adjustment). In this final rule, we estimate that 2,666 hospitals will have their base operating DRG payments reduced by their proxy FY 2016 hospital-specific readmissions adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately $420 million in FY 2016, an increase of $6 million over the estimated FY 2015 savings.

5. Effects of Changes Under the FY 2016 Hospital Value-Based Purchasing (VBP) Program

In section IV.F. of the preamble of this final 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 2016 through a reduction to the FY 2016 base operating DRG payment for each discharge of 1.75 percent, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2017 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.

We estimate the available pool of funds for value-based incentive payments in the FY 2016 program year, which, in accordance with section 1886(o)(7)(C)(iv) of the Act, will be 1.75 percent of base operating DRG payments, or a total of approximately $1.50 billion. This estimated available pool for FY 2016 is based on the historical pool of hospitals that were eligible to participate in the FY 2015 program year and the payment information from the March 2015 update to the FY 2014 MedPAR file.

The estimated impacts of the FY 2016 program year by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2015 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 March 2015 update to the FY 2014 MedPAR file. The proxy adjustment factors can be found in Table 16A associated with this final rule (available via the Internet on the CMS Web site).

The impact analysis shows that, for the FY 2016 program year, the number of hospitals that will receive an increase in base operating DRG payment amount is higher than the number of hospitals that will receive a decrease. Among urban hospitals, those in the New England, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific regions will have an increase, on average, in the base operating DRG payment amount. Urban hospitals in the Middle Atlantic region will receive an average decrease in the base operating payment amount. Among rural hospitals, those in all regions will have an increase, on average, in base operating DRG payment amounts.

On average, hospitals that receive a higher percent of DSH payments will receive decreases in the base operating DRG payment amount. With respect to hospitals' Medicare utilization (MCR), those hospitals with an MCR above 65 percent will have the largest increase, on average, in base operating DRG payment amounts.

Nonteaching hospitals will have an average increase, and teaching hospitals will experience an average decrease, in the base operating DRG payment amount.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT CHANGES RESULTING FROM THE FY 2016 HOSPITAL VBP PROGRAM

	Number of hospitals	Average percentage change
By Geographic Location:		
All Hospitals	3,089	0.132
Large Urban	1,263	0.046

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT CHANGES RESULTING FROM THE FY 2016 HOSPITAL VBP PROGRAM—Continued

	Number of hospitals	Average percentage change
Other Urban	1,066	0.137
Rural Area	760	0.269
Urban hospitals	*2,329*	*0.088*
0–99 beds	524	0.492
100–199 beds	735	0.028
200–299 beds	437	−0.054
300–499 beds	422	−0.079
500 or more beds	211	−0.082
Rural hospitals	*760*	*0.269*
0–49 beds	258	0.445
50–99 beds	298	0.251
100–149 beds	119	0.079
150–199 beds	46	0.035
200 or more beds	39	0.094
By Region:		
Urban by Region	2,329	0.088
New England	116	0.045
Middle Atlantic	306	−0.058
South Atlantic	389	0.037
East North Central	376	0.106
East South Central	139	0.042
West North Central	154	0.366
West South Central	332	0.178
Mountain	157	0.047
Pacific	360	0.095
Rural by Region	760	0.269
New England	20	0.384
Middle Atlantic	55	0.170
South Atlantic	123	0.330
East North Central	114	0.280
East South Central	135	0.269
West North Central	93	0.333
West South Central	140	0.161
Mountain	56	0.346
Pacific	24	0.228
By MCR Percent:		
0–25	583	0.110
25–50	2,041	0.107
50–65	322	0.204
Over 65	72	0.323
Missing	71	0.513
BY DSH Percent:		
0–25	1,462	0.254
25–50	1,336	0.054
50–65	149	−0.107
Over 65	142	−0.139
By Teaching Status:		
Non-Teaching	2,077	0.208
Teaching	1,012	−0.023

Actual FY 2016 program year's TPSs will not be reviewed and corrected by hospitals until after this FY 2016 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2015 program year are used for the updated impact analysis in this final rule.

6. Effects of Changes to the HAC Reduction Program for FY 2016

In section IV.G. of the preamble of this final rule, we discuss the changes to the HAC Reduction Program for FY 2016. We note that section 3008 of the Affordable Care Act added section 1886(p) to the Act to provide an incentive for certain hospitals to reduce the incidence of HACs. Section 1886(p) of the Act requires the Secretary to make an adjustment to payments to ''applicable hospitals'' effective beginning on October 1, 2014 and for subsequent program years. We refer readers to section V.I.1.a. 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 further description of our policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104). These policies describe The general framework for implementation of the HAC Reduction Program including: (a) The relevant definitions applicable to the program; (b) the payment adjustment under the program; (c) the measure selection and conditions for the program, including a risk-adjustment and scoring methodology; (d) performance scoring; (e) 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 (f) limitation of administrative and judicial review. We are not making any changes to these policies for the implementation of the FY 2016 HAC Reduction Program.

We note that hospitals received a payment reduction for the first time in FY 2015. The table and analysis that we are presenting

below are a simulation of the FY 2016 HAC Reduction Program using historical data. We note that, as described earlier in this final rule, because scores will undergo 30-day review and correction by the hospitals that will not conclude until after the publication of this final rule, we are not providing hospital-level data or a hospital-level payment impact in conjunction with this FY 2016 IPPS/LTCH PPS final rule.

For FY 2016, we note that we finalized a Total HAC Score methodology in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104) that assigns weights for Domain 1 and Domain 2 at 25 percent and 75 percent, respectively. The table below presents data on the estimated proportion of hospitals in the worst-performing quartile of the Total HAC Score by hospital characteristic, based on this methodology.

To estimate the impact of the FY 2016 HAC Reduction Program, we used AHRQ Patient Safety Indicator (PSI) 90 measure results based on Medicare fee-for-service (FFS) discharges from July 2012 through June 2014 and version 4.5a of the AHRQ software. For CDC Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), and Surgical Site Infection (SSI) 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, 2013 and December 31, 2014. To analyze the results by hospital characteristic, we used the FY 2016 Proposed Rule Impact File. Of the 3,272 hospitals included in this analysis, 3,269 hospitals had information for geographic location, region, bed size, DSH percent, and teaching status; 3,256 had information for ownership; and 3,137 had information for MCR percent. These differences in the number of hospitals listed for each characteristic are due to the source of the hospital characteristic data. Maryland hospitals and hospitals without a Total HAC score are not included in the identification of the worst-performing quartile for the HAC Reduction Program in FY 2016, and therefore are not represented in the table below. (For a discussion of the program's applicability to Maryland hospitals, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50089.)

The third column in the table (Percent) indicates the percent of hospitals in each category of the specified characteristic. For example, within geographic location, 40.5 percent of hospitals (or 1,323 hospitals) are characterized as large urban, 33.9 percent of hospitals (or 1,109 hospitals) are characterized as other urban, and 25.6 percent of hospitals (or 837 hospitals) are characterized as rural. The fifth column in the table (Percent with characteristic) indicates the proportion of hospitals for each characteristic that we estimate will be in the worst-performing quartile of Total HAC Scores and will receive a payment reduction under the FY 2016 HAC Reduction Program. For example, with regards to geographic location, 27.4 percent of hospitals (or 362 hospitals) characterized as large urban will be subject to a payment reduction; 25.2 percent of hospitals (or 279 hospitals) characterized as other urban will be subject to a payment reduction; and 19.5 percent of hospitals (or 163 hospitals) characterized as rural will be subject to a payment reduction.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORE FOR THE FY 2016 HAC REDUCTION PROGRAM

[by hospital characteristic]

Hospital characteristic	Number of hospitals [a]	Percent [b]	Number of hospitals in the worst-performing quartile	Percent of hospitals in the worst-performing quartile [c]
Total [d]	3,272	100.0	807	24.4
By Geographic Location				
All hospitals:				
Large urban [e]	1,323	40.5	362	27.4
Other urban	1,109	33.9	279	25.2
Rural	837	25.6	163	19.5
Urban hospitals:				
1–99 beds	619	25.5	140	22.6
100–199 beds	739	30.4	158	21.4
200–299 beds	438	18.0	108	24.7
300–399 beds	272	11.2	87	32.0
400–499	152	6.3	67	44.1
500 or more beds	212	8.7	81	38.2
Rural hospitals:				
1–49 beds	332	39.7	90	27.1
50–99 beds	298	35.6	46	15.4
100–149 beds	120	14.3	10	8.3
150–199 beds	47	5.6	8	17.0
200 or more beds	40	4.8	9	22.5
By Region:				
Urban by region				
New England	115	4.7	42	36.5
Mid-Atlantic	315	13.0	102	32.4
South Atlantic	397	16.3	94	23.7
East North Central	388	16.0	79	20.4
East South Central	147	6.0	31	21.1
West North Central	161	6.6	35	21.7
West South Central	369	15.2	87	23.6
Mountain	165	6.8	54	32.7
Pacific	375	15.4	117	31.2
Rural by region:.				
New England	20	2.4	7	35.0
Mid-Atlantic	55	6.6	11	20.0
South Atlantic	127	15.2	21	16.5
East North Central	115	13.7	22	19.1
East South Central	157	18.8	17	10.8
West North Central	105	12.5	34	32.4
West South Central	162	19.4	28	17.3

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORE FOR THE FY 2016 HAC REDUCTION PROGRAM—Continued

[by hospital characteristic]

Hospital characteristic	Number of hospitals [a]	Percent [b]	Number of hospitals in the worst-performing quartile	Percent of hospitals in the worst-performing quartile [c]
Mountain	70	8.4	20	28.6
Pacific	26	3.1	3	11.5
By DSH Percent [f]				
0–24	1,563	47.8	349	22.3
25–49	1,379	42.2	342	24.8
50–64	163	5.0	55	33.7
65 and over	164	5.0	58	35.4
By Teaching Status: [g]				
Non-teaching	2,247	68.7	464	20.6
Fewer than 100 residents	776	23.7	216	27.8
100 or more residents	246	7.5	124	50.4
By Urban Teaching and DSH: [f, g]				
Teaching and DSH	841	25.7	298	35.4
Teaching and no DSH	126	3.9	33	26.2
No teaching and DSH	1,043	31.9	212	20.3
No teaching and no DSH	422	12.9	98	23.2
Non-urban	837	25.6	163	19.5
By Type of Ownership:				
Voluntary	1,889	58.0	467	24.7
Proprietary	856	26.3	186	21.7
Government	511	15.7	142	27.8
By MCR Percent:				
0–24	637	20.3	208	32.7
25–49	2,081	66.3	465	22.3
50–64	328	10.5	55	16.8
65 and over	91	2.9	18	19.8

SOURCE: Scores are based on AHRQ PSI 90 data from July 2012 through June 2014 and CLABSI, CAUTI, and SSI results from January 2013 to December 2014. Hospital Characteristics are based on the FY 2016 Proposed Rule Impact File.

[a] The total number of non-Maryland hospitals with a Total HAC Score and hospital characteristic data (3,269 for geographic location, bed size, and teaching status; 3,256 for type of ownership; and 3,137 for MCR) does not add up to the total number of non-Maryland hospitals with a Total HAC Score for the FY 2016 HAC Reduction Program (3,272) because 3 hospitals are not included in the FY 2016 Proposed Rule Impact File and not all hospitals have data for all characteristics.

[b] This column is the percent of all non-Maryland hospitals with each characteristic that have a Total HAC Score for the FY 2016 HAC Reduction Program and are included in the FY 2016 Proposed Rule Impact File. Percentages may not sum to 100 due to rounding.

[c] This column is the percent of hospitals within each characteristic that we estimate would be in the worst-performing quartile.

[d] Total excludes the 47 Maryland hospitals and 36 hospitals without a Total HAC Score for FY 2016.

[e] Large urban hospitals are hospitals located in large urban areas (populations over 1 million).

[f] A hospital is considered to be a DSH hospital if it has a DSH patient percentage greater than zero.

[g] A hospital is considered to be a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

7. Effects of Modification of the Simplified Cost Allocation Methodology Used by Hospitals

In section IV.H. of the preamble of this final rule, we discuss our modification of the simplified cost allocation methodology set forth in CMS Pub. 15–2, Chapter 40, Section 4020. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24514 through 24515), we had proposed to limit the election of the simplified cost allocation methodology to cost reporting periods beginning before October 1, 2015, because the allocation of the costs of capital-related movable equipment using this methodology yields less precise calculated CCRs. After consideration of the public comments we received, we are not finalizing the proposal to limit the election of the simplified cost allocation methodology. Instead, we are retaining the simplified cost allocation methodology with some modifications to afford hospitals using the simplified cost allocation methodology flexibility to obtain approval from their MACs to use dollar value as an alternative statistical basis to square footage for capital-related moveable equipment. Based on FY 2013 HCRIS data, less than 100 hospitals are using the simplified cost allocation methodology. Hospitals using the simplified cost allocation methodology (that is, hospitals using each and every statistical basis within the list of cost centers under the simplified cost allocation methodology) may continue their use of these statistical bases, with the added flexibility to request approval from their MACs to use the dollar value statistical basis for capital-related moveable equipment in accordance with the instructions set forth in CMS Pub. 15–1, Section 2313. In this regard, hospitals using the simplified cost allocation methodology will no longer be required to use the square footage statistical basis for capital-related moveable equipment but will be provided greater flexibility to request approval to use the statistical basis of dollar value, which may be better suited to their cost allocation needs. With this modification, we believe there will be no disruption of cost reporting practices for hospitals, regardless of whether or not they use the simplified cost allocation methodology. Hospitals using one or more, but not all, of the statistical bases under the simplified cost allocation methodology are not considered to be using the simplified cost allocation methodology. Rather, they are considered to be using the standard cost-finding methodology with approved alternative bases. These hospitals may continue to use these previously approved statistical bases, consistent with current manual instructions set forth in CMS Pub. 15–1, Section 2313. We believe that these finalized changes will not have a significant impact on the operations of a substantial number of small rural hospitals. We also do not believe that the finalized changes will affect beneficiary access to care, as affected hospitals will continue to be paid for services provided to Medicare beneficiaries.

8. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.I. of the preamble of this final rule, for FY 2016, we discuss our

implementation of section 410A of Public Law 108–173, as amended, which requires the Secretary to conduct a demonstration that would modify reimbursement for inpatient services for up to 30 rural community hospitals. Section 410A(c)(2) 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. As discussed in section IV.I. of the preamble of this final rule, in the IPPS final rules for each of the previous 11 fiscal years, we have 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 are adjusting the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are applying 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.

We are adjusting the national IPPS rates according to the methodology set forth in section IV.I.2. of the preamble of this final rule. We note that the phase-out of the demonstration has begun with the 7 ''pre-expansion'' participating hospitals that were selected for the demonstration during 2004 and 2008 concluding their participation during FY 2015. Therefore, we have not included the financial experience of these hospitals in the estimated demonstration cost for FY 2016. Of the 15 hospitals that entered the demonstration in 2011 and 2012 under the Affordable Care Act expansion, 11 hospitals are scheduled to end their participation in the demonstration during FY 2016. Eight of these 11 hospitals are scheduled to end their participation in the demonstration prior to September 30, 2016. For each of these 8 hospitals, we estimate the reasonable cost amount and the amount that would otherwise be paid without the demonstration for FY 2016 on a prorated basis, multiplying the estimated amounts for each hospital (as derived from ''as submitted'' cost reports for cost reporting periods ending in CY 2013) by the fraction of the number of months that it will participate in the demonstration during FY 2016 in relation to the total 12-month period. Accordingly, the budget neutrality offset amount used to determine the adjustment to the national IPPS rates to account for estimated demonstration costs for FY 2016 for these 15 hospitals is $26,044,620. In addition, in this final rule, we are subtracting from the budget neutrality offset amount for FY 2016 the following: (1) The amount by which the budget neutrality offset amount that was finalized in the FY 2009 IPPS/LTCH PPS final rule exceeded the actual costs of the demonstration for FY 2009 (as shown in the finalized cost reports for hospitals that participated in FY 2009 and had cost reporting periods beginning in FY 2009) ($8,457,452); and (2) the amount by which the budget neutrality offset amount that was finalized for FY 2010 to account for the demonstration costs in FY 2010 (as set forth in the FY 2010 and 2011 IPPS final rules) exceeded the actual costs of the demonstration during FY 2010 (similarly as shown in the finalized cost reports for hospitals that participated in FY 2010 and had for cost reporting periods beginning in 2010). This amount is $4,751,550. Therefore, the resulting total ($12,835,618) is the amount for which an adjustment to the IPPS rates for FY 2016 is calculated.

9. Effects of the Changes to MS–DRGs Subject to the Postacute Care Transfer Policy and the Special Payment Policy

In section IV.J. of the preamble to this final rule, we discuss changes to the list of MS–DRGs subject to the postacute care transfer policy and the DRG special payment policy. As reflected in Table 5 listed in section VI. of the Addendum to this final rule (which is available via the Internet on the CMS Web site), using criteria set forth in regulations at § 412.4, we evaluated MS–DRG charge, discharge, and transfer data to determine which MS–DRGs qualify for the postacute care transfer and DRG special payment policies. We note that we are not making any changes in these payment policies in this FY 2016 final rule. We are including two new MS–DRGs on the list of MS–DRGs subject to the postacute care transfer policy and the DRG special payment policy as a result of our revisions of the MS–DRG classifications for FY 2016. Specifically, we are establishing that two new MS–DRGs will qualify for the postacute care transfer policy and the DRG special payment policy in FY 2016. Column 4 of Table I in this Appendix A shows the effects of the changes to the MS–DRGs and the relative payment weights and the application of the 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 in the status of MS–DRG postacute care transfer and special payment policies. We refer readers to section I.G. of this Appendix A for a detailed discussion of payment impacts due to MS–DRG reclassification policies.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the March 2015 update of the FY 2014 MedPAR file and the March 2015 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2015 update of the most recently available hospital cost report data (FYs 2012 and 2013) 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 below.

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 March 2015 update of the FY 2014 MedPAR file, we simulated payments under the capital IPPS for FY 2015 and FY 2016 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (for example, Indian Health Service hospitals and 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 capital IPPS payments in FY 2016 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 will increase by 0.5 percent in both FYs 2015 and 2016.
- We estimate that Medicare discharges will be approximately 11.3 million in FY 2015 and 11.2 million in FY 2016.
- 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 final rule, the update is 1.3 percent for FY 2016.
- In addition to the FY 2016 update factor, the FY 2016 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 0.9973 and an outlier adjustment factor of 0.9365. As discussed in section VI.C. of the preamble of this final rule, we are not making an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rates for FY 2016.

2. Results

We used the actuarial model described above to estimate the potential impact of our changes for FY 2016 on total capital payments per case, using a universe of 3,369 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the March 2015 update of the FY 2014 MedPAR file, the March 2015 update to the PSF, and the most recent cost report data from the March 2015 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2015 and estimated total payments per case for FY 2016 based on the FY 2016 payment policies. Column 2 shows estimates of payments per case under our model for FY 2015. Column 3 shows estimates of payments per case under our model for FY 2016. Column 4 shows the total percentage change in payments from FY 2015 to FY 2016. The change represented in Column 4 includes the 1.3 percent update to the capital Federal rate and other 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 2016 are expected to increase as compared to capital payments per case in FY 2015. This expected increase is due to the approximately 0.85 percent increase in the capital Federal rate for FY 2016 as compared to the FY 2015 capital Federal rate and, to a lesser degree, changes to the MS–DRG reclassifications and recalibrations and changes in outlier payments. (For a discussion of the determination of the capital Federal rate, we refer readers to section III.A. of the Addendum to this final rule.) The increase in capital payments per case due to the effects of changes to the MS–DRG reclassifications and recalibrations is expected to be slightly greater for urban hospitals, as are the increases in capital payments per case due to changes in outlier payments. However, half of the urban areas and most of the rural areas are expected to experience a somewhat smaller projected increase in capital payments per case due to the effects of changes to the GAFs. These regional effects of the changes to the GAFs on capital payments are consistent with the projected changes in payments due to changes in the wage index (and policies affecting the wage index) as shown in Table I in section I.G. of this Appendix.

The net impact of these changes is an estimated 2.3 percent change in capital payments per case from FY 2015 to FY 2016 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, hospitals in all classifications (urban and rural) will experience an increase in capital IPPS payments per case in FY 2016 as compared to FY 2015. Capital IPPS payments per case for hospitals in ''large urban areas'' have an estimated increase of 2.5 percent, while hospitals in rural areas, on average, are expected to experience a 1.4 percent increase in capital payments per case from FY 2015 to FY 2016. Capital IPPS payments per case for ''other urban hospitals'' are estimated to increase 2.1 percent. The primary factor contributing to the difference in the projected increase in capital IPPS payments per case for urban hospitals as compared to rural hospitals is the changes in the GAFs. Rural hospitals in all but two rural regions are projected to experience a decrease in capital payments due to the effect of changes in the GAFs, while hospitals in only half of the urban regions are projected to experience a decrease in capital payments due to the effect of the changes in the GAFs.

The comparisons by region show that the estimated increases in capital payments per case from FY 2015 to FY 2016 in urban areas range from a 3.1 percent increase for the Pacific urban region to a 1.1 percent increase for the New England urban region. For rural regions, the Pacific rural region is projected to experience the largest increase in capital IPPS payments per case of 3.0 percent; the West South Central rural region is projected to experience the smallest increase in capital IPPS payments per case of 0.1 percent. The change in the GAFs is the main factor for the West South Central rural region experiencing the smallest projected increase in capital IPPS payments among rural regions, and it is also the main contributor for the smallest projected increase in capital IPPS payments for the New England urban region. However, the changes in the GAFs have the opposite effect for both the Pacific urban and Pacific rural regions where they are a primary contributor to the expected larger than average increase in capital IPPS payments per case.

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 2015 to FY 2016. The increase in capital payments for voluntary and proprietary hospitals is estimated to be 2.3 percent. For government hospitals, the increase is estimated to be 2.4 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2016. 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 final rule for FY 2016, we show the average capital payments per case for reclassified hospitals for FY 2016. Urban reclassified hospitals are expected to experience an increase in capital payments of 2.8 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 2.2 percent. The estimated percentage increase for rural reclassified hospitals is 1.8 percent, and for rural nonreclassified hospitals, the estimated percentage increase is 1.1 percent.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2015 Payments Compared to FY 2016 Payments]

	Number of hospitals	Average FY 2015 payments/case	Average FY 2016 payments/case	Change
By Geographic Location:				
All hospitals	3,369	871	890	2.3
Large urban areas (populations over 1 million)	1,393	963	987	2.5
Other urban areas (populations of 1 million of fewer)	1,140	833	851	2.1
Rural areas	836	591	599	1.4
Urban hospitals	2,533	904	925	2.3
0–99 beds	668	736	750	1.9
100–199 beds	778	788	805	2.2
200–299 beds	445	825	844	2.3
300–499 beds	428	920	943	2.4
500 or more beds	214	1,080	1,106	2.4
Rural hospitals	836	591	599	1.4
0–49 beds	329	490	497	1.5
50–99 beds	297	549	557	1.6
100–149 beds	121	591	598	1.2
150–199 beds	48	645	652	1.0
200 or more beds	41	706	715	1.3
By Region:				
Urban by Region	2,533	904	925	2.3
New England	120	996	1,008	1.1

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2015 Payments Compared to FY 2016 Payments]

	Number of hospitals	Average FY 2015 payments/case	Average FY 2016 payments/case	Change
Middle Atlantic	318	1,001	1,032	3.0
South Atlantic	407	805	823	2.2
East North Central	396	868	889	2.3
East South Central	150	768	780	1.6
West North Central	166	887	902	1.6
West South Central	384	817	835	2.1
Mountain	161	936	956	2.0
Pacific	380	1,150	1,186	3.1
Puerto Rico	51	403	408	1.4
Rural by Region	836	591	599	1.4
New England	22	822	828	0.7
Middle Atlantic	55	580	582	0.3
South Atlantic	128	554	566	2.3
East North Central	116	616	626	1.6
East South Central	164	536	542	1.1
West North Central	101	635	643	1.3
West South Central	165	524	524	0.1
Mountain	61	660	674	2.1
Pacific	24	768	791	3.0
By Payment Classification:				
All hospitals	3,369	871	890	2.3
Large urban areas (populations over 1 million)	1,386	964	988	2.5
Other urban areas (populations of 1 million of fewer)	1,090	837	855	2.2
Rural areas	893	608	615	1.0
Teaching Status:				
Non-teaching	2,326	739	754	2.1
Fewer than 100 Residents	794	848	866	2.2
100 or more Residents	249	1,227	1,259	2.6
Urban DSH:				
100 or more beds	1,593	928	950	2.4
Less than 100 beds	328	662	677	2.3
Rural DSH:				
Sole Community (SCH/EACH)	260	576	580	0.7
Referral Center (RRC/EACH)	347	639	647	1.2
Other Rural:				
100 or more beds	31	575	573	−0.4
Less than 100 beds	157	504	512	1.7
Urban teaching and DSH:				
Both teaching and DSH	855	1,003	1,027	2.5
Teaching and no DSH	122	899	919	2.2
No teaching and DSH	1,066	780	797	2.3
No teaching and no DSH	433	797	816	2.3
Rural Hospital Types:				
Non special status hospitals	2,562	904	926	2.4
RRC/EACH	189	729	737	1.1
SCH/EACH	327	665	672	1.1
SCH, RRC and EACH	126	721	733	1.6
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2016 Reclassifications:				
All Urban Reclassified	551	923	948	2.8
All Urban Non-Reclassified	1,925	902	922	2.2
All Rural Reclassified	279	623	634	1.8
All Rural Non-Reclassified	504	545	551	1.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	46	600	589	−1.8
Type of Ownership:				
Voluntary	1,934	884	904	2.3
Proprietary	879	785	803	2.3
Government	529	917	938	2.4
Medicare Utilization as a Percent of Inpatient Days:				
0–25	533	1,046	1,074	2.7
25–50	2,134	876	896	2.3
50–65	571	717	731	1.9
Over 65	97	523	534	2.1

J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2016. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify those policies, and present rationales for our final decisions as well as alternatives that were considered. In this section of Appendix A to this final rule, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 419 LTCHs included in this impacts analysis, which includes data for 78 nonprofit (voluntary ownership control) LTCHs, 326 proprietary LTCHs, and 15 LTCHs that are government-owned and operated. (We note that, although there are currently approximately 430 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2016 MS–LTC–DRG relative weights (discussed in section VII.C.3.c. of the preamble of this final rule)). In the impact analysis, we used the payment rate, factors, and policies presented in this final rule, including the application of the new site neutral payment rate required by section 1886(m)(6)(A) of the Act (discussed in section VII.B. of the preamble of this final rule), the 1.7 percent annual update to the LTCH PPS standard Federal payment rate in accordance with section 1886(m)(5)(C) of the Act (which is based on the full estimated increase of the LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act), the update to the MS–LTC–DRG classifications and relative weights for the LTCH PPS standard Federal payment rate cases, the update to the wage index values and labor-related share for the LTCH PPS standard Federal payment rate cases, and the best available claims and CCR data to estimate the change in payments for FY 2016.

Under the new dual rate LTCH PPS payment structure, there will be two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, as discussed in section VII.B. of the preamble of this final rule, we provide 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) based on the LTCH PPS standard Federal payment rate. In addition, consistent with the statute, we are establishing that 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, under our finalized policies, 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 will be paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. As discussed more fully in section VII.B.4.b. of the preamble of this final rule, the transitional payment amount for site neutral payment rate cases is a blended payment rate, which will be calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under new § 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 419 LTCHs in our database that were considered in the analyses used for this final rule, we estimate that overall LTCH PPS payments in FY 2016 will decrease by approximately 4.6 percent (or approximately $250 million). This projection takes into account estimated payments for LTCH cases that would have met the new patient-level criteria and been paid the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of the discharge, and estimated payments for LTCH cases that would not have met those new patient-level criteria and been paid under the site neutral payment rate if that rate had been in effect at the time of the discharge described below.

Because the statute specifies that the site neutral payment rate effective date for a given LTCH is determined based on the date on which that LTCH's cost reporting period begins on or after October 1, 2015, our estimate of FY 2016 LTCH PPS payments for site neutral payment rate cases includes an adjustment to account for this rolling effective date. Our approach, applied to the FY 2014 data that were used for the analyses in this final rule, accounts for the fact that LTCHs with cost reporting periods that begin after October 1, 2015, will continue to be paid for all discharges (including those that do not meet the patient-level criteria for exclusion from the site neutral payment rate) at the LTCH PPS standard Federal payment rate until the start of their first cost reporting period beginning after October 1, 2015. Therefore, in order to estimate total LTCH PPS payments for site neutral payment rate cases in FY 2016, we first identified LTCHs with cost reporting periods that would begin in the first quarter of FY 2016 (that is, October through December 2015), and modeled those LTCHs estimated FY 2016 site neutral payment rate payments based on the transitional blended payment rate. We then modeled the estimated first quarter FY 2016 payments to LTCHs with cost reporting periods that would begin after the first quarter of FY 2016 using the LTCH PPS standard Federal payment rate. We then identified the LTCHs with cost reporting periods that would begin in each of the remaining three quarters of FY 2016, and applied an analogous analysis to estimate payments in each respective quarter of FY 2016. (For full details on our method of estimating payments under our finalized policies for FY 2016, we refer readers to the description presented in section V.D.4. of the Addendum to the proposed rule.) We believe that this approach is a reasonable means of taking the rolling effective date into account when estimating FY 2016 payments. Based on the fiscal year start dates recorded in the March update of the Provider Specific File, of the 419 LTCHs in our database of LTCH claims from the March 2015 update of the FY 2014 MedPAR files used for this final rule, the following percentages apply in the approach described above: 11.24 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the first quarter of FY 2016; 29.88 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the second quarter of FY 2016; 10.73 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the third quarter of FY 2016; and 48.15 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the fourth quarter of FY 2016.

Based on the FY 2014 LTCH cases that were used for the analyses in this final rule, approximately 46 percent of LTCH cases would have been classified as site neutral payment rate cases if the site neutral payment rate had been in effect in FY 2014 (that is, 46 percent of such LTCH cases would not have met 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 2016 will not change significantly from the historical data. Taking into account the transitional blended payment rate and other policies applicable to the site neutral payment rate cases in FY 2016, and our approach to account for the rolling effective date for the new site neutral payment rate, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will decrease by approximately 14.8 percent (or approximately $300 million).

Approximately 54 percent of LTCH cases are expected to meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2016, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2016 will increase approximately 1.5 percent (or approximately $50 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2016 is primarily a result of the 1.7 percent annual update to the LTCH PPS standard Federal payment rate for FY 2016 (discussed in section V.A. of the Addendum to this final rule) and an estimated decrease in HCO payments for these cases.

Based on the 419 LTCHs that were represented in the FY 2014 LTCH cases that were used for the analyses in this final rule, we estimate that aggregate FY 2016 LTCH PPS payments will be approximately $5.150 billion, as compared to estimated aggregate FY 2015 LTCH PPS payments of approximately $5.400 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $250 million. Because the combined distributional effects and estimated payment changes exceed $100

million, this final rule is a major economic rule. We note that this estimated $250 million decrease in LTCH PPS payments in FY 2016 (which includes estimated payments for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases) does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of what is in this rule.

The LTCH PPS standard Federal payment rate for FY 2015 is $41,043.71. For FY 2016, we are establishing a LTCH PPS standard Federal payment rate of $41,762.85, which reflects the 1.7 percent annual update to the LTCH PPS standard Federal payment rate and the area wage budget neutrality factor of 1.000513 to ensure that the changes in the wage indexes and labor-related share do not influence aggregate 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 establishing an LTCH PPS standard Federal payment rate of $40,941.55. This reduced LTCH PPS standard Federal payment rate reflects the updates described above as well as the required 2.0 percentage point reduction to the annual update for failure to submit data to the LTCH QRP. We note that the factors described above to determine the FY 2016 LTCH PPS standard Federal payment rate are applied to the FY 2015 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xi) (that is, $41,762.85).

Table IV (column 6) shows that the estimated change attributable solely to the annual update to the LTCH PPS standard Federal payment rate is projected to result in an increase of 1.4 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016, on average, for all LTCHs. In addition to the annual update to the LTCH PPS standard Federal payment rate for FY 2016, this estimated increase in aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases of 1.4 percent shown in column 6 of Table IV also includes estimated payments for SSO cases that will be paid using special methodologies that are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the penalty 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 LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases is somewhat less than the 1.7 percent annual update for FY 2016.

As discussed in section V.B. of the Addendum to this final rule, we are updating the wage index values for FY 2016 based on the most recent available data, and we are continuing to use labor market areas based on the OMB CBSA delineations. In addition, we are slightly lowering the labor-related share from 62.306 percent to 62.0 percent under the LTCH PPS for FY 2016, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs based on the FY 2009-based LTCH-specific market basket. We also are applying an area wage level budget neutrality factor of 1.000513 to ensure that the changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases, which increases the LTCH PPS standard Federal payment rate by approximately 0.095 percent.

We currently estimate total HCO payments for LTCH PPS standard Federal payment rate cases are projected to decrease from FY 2015 to FY 2016. Using the FY 2014 LTCH cases that were used for the analyses in this final rule, we estimate that the FY 2015 HCO threshold of $14,972 (as established in the FY 2015 IPPS/LTCH PPS final rule) will result in estimated HCO payments for LTCH PPS standard Federal payment rate cases in FY 2015 that are above the estimated 8 percent target. Specifically, we currently estimate that HCO payments for LTCH PPS standard Federal payment rate cases will be approximately 8.1 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2015. Combined with our estimate that FY 2016 HCO payments for LTCH PPS standard Federal payment rate cases would be 8.0 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2016, this results in the estimated decrease of approximately 0.1 percent between FY 2015 and FY 2016.

In calculating these estimated HCO payments we increased estimated costs by our actuaries' projected market basket percentage increase factor. This increase in estimated costs also results in a projected increase in SSO payments in FY 2016. We estimate that these increased SSO payments in FY 2016 will increase total payments for LTCH PPS standard Federal payment rate cases by 0.2 percent. (Payments for SSO cases represent approximately 13 percent of the estimated total payments for LTCH PPS standard Federal payment rate cases.)

Table IV below shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2016 by comparing estimated FY 2015 LTCH PPS payments to estimated FY 2016 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) The projected increase in payments from FY 2015 to FY 2016 for LTCH PPS standard Federal payment rate cases of 1.5 percent is attributable to the impacts of the change to the LTCH PPS standard Federal payment rate (1.4 percent in Column 6) and the effect of the estimated decrease in HCO payments for LTCH PPS standard Federal payment cases (−0.1 percent), and the estimated increase in payments for SSO cases (0.2 percent).

As we discuss in detail throughout this final rule, based on the most recent available data, we believe that the provisions of this final 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 will 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 a 1.5 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases. This estimated impact is based on the FY 2014 data for the 21 rural LTCHs (out of 419 LTCHs) that were used for the analyses in this final rule. We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

3. Anticipated Effects of 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 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 new dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. As discussed in section VII.B. of the preamble of this final rule, 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) will be paid based on the LTCH PPS standard Federal payment rate. LTCH discharges that will be paid at the site neutral payment rate will generally be 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 will be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, under which the site neutral payment rate cases will be 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 for the discharge. (For additional details on the application of the site neutral payment rate beginning in FY 2016, we refer readers to section VII.B. of the preamble of this final rule.)

As discussed above in section I.J.1. of this Appendix, we project a decrease in aggregate LTCH PPS payments in FY 2016 of approximately $250 million. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $50 million and the projected decrease in payments to site neutral payment rate cases of approximately $300 million under the new dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section VII.B.7.b. of the preamble of this final 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 final rule to project estimated FY 2016 LTCH PPS payments (that is, FY 2014 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV below only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3 of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Below we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

Under the new dual rate LTCH PPS payment structure, the statute establishes two distinct payment rates for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Under that statute, any discharges that occur on or after October 1, 2015, but prior to the start of the LTCH's FY 2016 cost reporting period will be paid at the LTCH PPS standard Federal payment rate. On or after the start of an LTCH's FY 2016 cost reporting period, discharges are paid based on the nature of the case. As described previously, LTCH PPS standard Federal payment rate cases are defined as LTCH discharges that will meet the patient-level criteria to be excluded from the typically lower site neutral payment rate, and site neutral payment rate cases are defined as LTCH discharges that will not meet the patient-level criteria and will generally be paid the generally lower site neutral payment rate. For discharges occurring in cost reporting periods beginning in FY 2016 or 2017, however, the statute specifies that site neutral payment rate cases will be paid based on a transitional payment method that will be calculated as 50 percent of the applicable site neutral payment rate amount and 50 percent of the applicable LTCH PPS standard Federal payment rate.

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is set forth under § 412.515 through § 412.536. 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. As explained previously, under our application of the new dual rate LTCH PPS payment structure required under section 1886(m)(6) of the Act, the LTCH PPS standard Federal payment rate would generally only be 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). Under the new statutory changes to the LTCH PPS, LTCH discharges that will not meet the patient-level criteria for exclusion will be 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 will be able to receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this final rule on different categories of LTCHs for FY 2016, it is necessary to estimate payments per discharge for FY 2015 using the rates, factors, and the policies established in the FY 2015 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2016 using the rates, factors, and the policies finalized in this FY 2016 IPPS/LTCH PPS final rule (as discussed in section VII. of the preamble of this final rule and section V. of the Addendum to this final rule). As discussed elsewhere in this 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 SSO and HCO cases in each year. The resulting analyses can then be used to compare how our finalized 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, FY 2012 through FY 2013 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 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 finalized policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FYs 2015 and 2016 payments on a case-by-case basis using historical LTCH claims from the FY 2014 MedPAR files that 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 those cases. For modeling FY 2015 LTCH PPS payments, we used the FY 2015 standard Federal rate of $41,043.71, or $40,240.51 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP, which reflects the 2.0 percentage points reduction required by section 1886(m)(5)(C) of the Act. Similarly, for modeling FY 2016 LTCH PPS standard Federal payment rate payments, we used the FY 2016 standard Federal payment rate of $41,762.85, or $40,941.55 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP, again, to reflect the 2.0 percentage points reduction required by section 1886(m)(5)(C) of the Act. 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 2015 LTCH PPS payments, we used the current FY 2015 labor-related share (62.306 percent); the wage index values established in the Tables 12A through 12D listed in the Addendum to the FY 2015 IPPS/LTCH PPS final rule (which are available via the Internet on the CMS Web site), including the transitional blended wage index for the implementation of the CBSA delineations in FY 2015; the FY 2015 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $14,972 (as discussed in section V.D. of the Addendum to that final rule) and the FY 2015 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2015 nonlabor-related share (37.694 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2016 LTCH PPS payments, we used the FY 2016 LTCH PPS labor-related share (62.0 percent), the FY 2016 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are also available via the Internet on the CMS Web site), the FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $16,423 (as discussed in section V.D.3. of the Addendum to this final rule), and the FY 2016 COLA factors (shown in the table in section V.C. of the Addendum to this final rule) to adjust the FY 2016 nonlabor-related share (38.0 percent) for LTCHs located in Alaska and Hawaii.

As discussed above, our impact analysis reflects an estimated change in payments for SSO cases, as well as an estimated decrease in HCO payments for LTCH PPS standard Federal payment rate cases (as described previously in section I.J.1. of this Appendix). In modeling payments for SSO and HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 4.6 percent (determined by the Office of the Actuary) to update the 2014 costs of each case.

The impacts presented below reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2015 to FY 2016 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2015 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described above).
- The fifth column shows the estimated FY 2016 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described above).
- 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 2015 to FY 2016 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh 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 2015 to FY 2016 for changes to the area wage level adjustment (that is, the wage indexes and the labor-related share), including the application of an area wage level budget neutrality factor (as discussed in section V.B. of the Addendum to this final rule).
- The eighth 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 2015 (Column 4) to FY 2016 (Column 5) for all changes (and includes the effect of estimated changes to HCO and SSO payments).

TABLE IV—IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR STANDARD PAYMENT RATE CASES FOR FY 2016

[Estimated FY 2015 payments compared to estimated FY 2016 payments]

LTCH Classification	Number of LTCHs	Number of LTCH PPS standard federal payment rate cases	Average FY 2015 LTCH PPS payment per case	Average FY 2016 LTCH PPS standard federal payment rate payment per case [1]	Percent change in payments per case due to the annual update to the LTCH PPS standard federal rate [2]	Percent change in payments per case due to changes to the area wage level adjustment with budget neutrality [3]	Percent change in payments per case from FY 2015 to FY 2016 for all changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
All Providers	419	73,745	$45,764	$46,448	1.4	0.0	1.5
By Location:							
Rural	21	2,167	38,203	38,565	1.3	−0.8	0.9
Urban	398	71,578	45,993	46,687	1.4	0.0	1.5
Large	200	42,605	48,296	48,995	1.4	0.0	1.4
Other	198	28,973	42,606	43,293	1.5	0.0	1.6
By Participation Date:							
Before Oct. 1983	14	2,077	42,350	43,513	1.5	0.5	2.7
Oct. 1983–Sept. 1993	43	9,068	51,140	51,812	1.4	0.0	1.3
Oct. 1993–Sept. 2002	180	32,620	44,461	45,190	1.5	−0.1	1.6
October 2002 and After	182	29,980	45,793	46,398	1.4	0.1	1.3
By Ownership Type:							
Voluntary	78	9,900	46,891	47,628	1.4	0.0	1.6
Proprietary	326	62,265	45,412	46,081	1.4	0.0	1.5
Government	15	1,580	52,605	53,544	1.4	0.1	1.8
By Region:							
New England	13	2,924	41,298	42,367	1.4	0.4	2.6
Middle Atlantic	29	5,315	51,549	51,942	1.5	−0.2	0.8
South Atlantic	61	12,139	45,783	46,357	1.4	0.0	1.3
East North Central	69	12,214	46,310	46,961	1.5	−0.1	1.4
East South Central	34	5,181	44,398	44,929	1.5	0.0	1.2
West North Central	25	3,759	45,421	46,069	1.4	−0.4	1.4
West South Central	130	19,551	40,235	40,932	1.4	−0.2	1.7
Mountain	33	4,281	47,101	47,782	1.4	−0.1	1.4
Pacific	25	8,381	56,045	57,071	1.4	0.5	1.8
By Bed Size:							
Beds: 0–24	26	1,286	41,622	42,489	1.4	0.4	2.1
Beds: 25–49	195	25,087	43,495	44,099	1.4	−0.1	1.4
Beds: 50–74	118	20,400	46,794	47,390	1.4	−0.1	1.3
Beds: 75–124	47	13,003	49,000	49,719	1.5	0.1	1.5
Beds: 125–199	21	7,734	45,647	46,458	1.5	0.1	1.8
Beds: 200 +	12	6,235	45,778	46,805	1.5	0.3	2.2

[1] Estimated FY 2016 LTCH PPS payments to LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to LTCH PPS standard Federal payment rate cases presented in the preamble of and the Addendum to this final rule.

[2] Percent change in estimated payments per discharge for LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2015 to FY 2016 for the annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2015 to FY 2016 for changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this final rule).

[4] Percent change in estimated payments per discharge for LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2015 (shown in Column 4) to FY 2016 (shown in Column 5), including all of the changes to the rates and factors applicable to LTCH PPS standard Federal payment rate cases presented in the preamble and the Addendum to this final rule. Note, this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (column 6) and the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments for LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

d. Results

Based on the FY 2014 LTCH cases (from 419 LTCHs) that were used for the analyses in this final rule, we have prepared the following summary of the impact (as shown above in Table IV) of the LTCH PPS payment rate and finalized policy changes for LTCH PPS standard Federal payment rate cases presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are expected to increase 1.5 percent, on average, for all LTCHs from FY 2015 to FY 2016 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. This estimated 1.5 percent increase in LTCH PPS payments per discharge to LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016 for all LTCHs (as shown in Table IV) was determined by comparing estimated FY 2016 LTCH PPS payments (using the payment rates and factors discussed in this final rule) to estimated FY 2015 LTCH PPS payments for LTCH discharges which would be LTCH PPS standard Federal payment rate cases if the new dual rate LTCH PPS payment structure had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are updating the LTCH PPS standard Federal payment rate for FY 2016 by 1.7 percent based on the latest estimate of the LTCH PPS market basket increase (2.4 percent), the reduction of 0.5 percentage point for the MFP adjustment, and the 0.2 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. 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 would be applied to the annual update to the LTCH PPS standard Federal rate. As explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the payment increase due to the 1.7 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 1.4 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2015 to FY 2016. This is because our estimate of the changes in payments due to the update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that will be paid using special methodologies that are not affected by the update to the LTCH PPS standard Federal payment rate. Consequently, we estimate that payments to LTCH PPS standard Federal payment rate cases may increase by less than 1.7 percent for certain hospital categories due to the annual update to the LTCH PPS standard Federal payment rate for FY 2016.

(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 overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016 for all hospitals is 1.5 percent. For rural LTCHs, the overall percent change for LTCH PPS standard Federal payment rate cases is estimated to be a 0.9 percent increase, while for urban LTCHs, we estimate the increase will be 1.5 percent. Large urban LTCHs are projected to experience an increase of 1.4 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016, and other urban LTCHs are projected to experience an increase of 1.6 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016, 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 44 percent) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002, and they are projected to experience a 1.6 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016, 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 a higher than average percent increase (2.6 percent) in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016, as shown in Table IV, which is primarily due to a projected larger than average increase in payments due to the changes to the area wage adjustment. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993. These LTCHs are projected to experience a 1.3 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016. LTCHs that began participating in the Medicare program after October 1, 2002, which treat approximately 40 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 1.3 percent increase in estimated payments from FY 2015 to FY 2016.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the most recent available data, approximately 18 percent of LTCHs are identified as voluntary (Table IV). The majority (nearly 78 percent) of LTCHs are identified as proprietary while government-owned and operated LTCHs represent approximately 4 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience an average increase in payments to LTCH PPS standard Federal payment rate cases of 1.6 percent; proprietary LTCHs are expected to experience an increase of 1.5 percent in payments to LTCH PPS standard Federal payment rate cases, while government-owned and operating LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases of 1.8 percent from FY 2015 to FY 2016.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2016 are projected to increase for LTCHs located in all regions in comparison to FY 2015. Of the 9 census regions, we project that the increase in estimated payments per discharge to LTCH PPS standard Federal payment rate cases would have the largest positive impact on LTCHs in the New England region (2.6 percent as shown in Table IV), which is largely attributable to the changes in the area wage level adjustment.

In contrast, LTCHs located in the Middle Atlantic region are projected to experience the smallest increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016. The lower than national average estimated increase in payments of 0.8 percent is primarily due to estimated decreases in payments associated with the changes to the area wage level adjustment.

(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. All bed size categories are projected to receive an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016. We project that large LTCHs (200+ beds) will experience a 2.2 percent increase in payments for LTCH PPS standard Federal payment rate cases, which is higher than the national average mostly due to a larger than average increase from the area wage level adjustment. Similarly, we project that both small LTCHs (0–24 beds) and relatively large LTCHs (125–199 beds) will experience a 2.1 percent increase and 1.8 percent increase, respectively, in payments for LTCH PPS standard Federal payment rate cases, which is also higher than the national average mostly due to increases in the area wage level adjustment. LTCHs with 25 to 49 beds and 75 to 124 beds are expected to experience a nearly average increase in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016 (1.4 percent and 1.5 percent, respectively), while LTCHs with between 50 and 74 beds are expected to experience a smaller than average increase in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016 (1.3 percent).

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2016 relative to FY

2015 of approximately $50 million (or approximately 1.5 percent) for the 419 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 final rule will result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2016 relative to FY 2015 of approximately $300 million (or approximately 14.8 percent) for the 419 LTCHs in our database. Therefore, we project that the provisions of this final rule will result in a decrease in estimated aggregate LTCH PPS payments to all cases in FY 2016 relative to FY 2015 of approximately $250 million (or approximately 4.6 percent) for the 419 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 final rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of the preamble of this final rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2018 payment determination.

In this final rule, we are finalizing our proposals to remove nine measures from the Hospital IQR Program for the FY 2018 payment determination and subsequent years:

- STK–01 Venous Thromboembolism (VTE) Prophylaxis (NQF #0434);
- STK–06: Discharged on Statin Medication* (NQF #0439);
- STK–08: Stroke Education* (NQF endorsement removed);
- VTE–1: Venous Thromboembolism Prophylaxis* (NQF #0371);
- VTE–2: Intensive Care Unit Venous Thromboembolism Prophylaxis* (NQF #0372);
- VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy* (NQF #0373);
- AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival* (NQF #0164);
- IMM–1 Pneumococcal Immunization (NQF #1653); and
- SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300).

(An asterisk (*) indicates that the measure is finalized for retention as an electronic clinical quality measure for the FY 2018 payment determination and subsequent years in section VIII.A.8. of the preamble of this final rule.)

The anticipated effect of removing these measures will be a reduction in the burden associated with the collection of chart-abstracted data. Due to the burden associated with the collection of chart-abstracted data, we estimate that the removal of AMI–7a will result in a burden reduction of approximately 219,000 hours across all hospitals. We estimate that the removal of the 6 VTE and STK chart-abstracted measures will result in a burden reduction of approximately 522,000 hours across all hospitals. The remaining two measures we are finalizing for removal have been previously suspended from the Hospital IQR Program. Therefore, their removal will not affect burden to hospitals. In total, we estimate that the removal of 9 measures will result in a total burden reduction of approximately 741,000 hours for the FY 2018 payment determination across all hospitals.

We are retaining six of the chart-abstracted measures finalized for removal as electronic clinical quality measures. We believe retaining some measures as electronic clinical quality measures will not affect the overall burden, as these measures were available for electronic reporting under previous requirements.

In this final rule, we are finalizing refinements, modified from what was proposed, to expand the measure cohorts for: (1) The Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization measure (NQF #0468); and (2) the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization measure (NQF #0506). Expanding the measure cohorts to include a broader population of patients adds a large number of patients, as well as additional hospitals, to these measures. However, this expansion will not affect the burden on hospitals or hospital performance on the Hospital IQR Program because these measures are claims-based and, therefore, require no additional effort on hospitals' part to submit the required data.

We also are finalizing our proposal to add seven of the eight measures we proposed to the Hospital IQR Program measure set. Four of these seven measures are added beginning with the FY 2018 payment determination and for subsequent years; three of these measures, addressing clinical episode-based payments, are added beginning with the FY 2019 payment determination and for subsequent years. Six of these measures are claims-based, and one measure is structural. The seven new measures are:

- Hospital Survey on Patient Safety Culture (structural);
- Kidney/UTI Clinical Episode-Based Payment (claims-based);
- Cellulitis Clinical Episode-Based Payment (claims-based);
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment (claims-based);
- Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based);
- Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (claims-based); and
- Excess Days in Acute Care after Hospitalization for Heart Failure (claims-based).

We are not finalizing our proposal to add the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure (claims-based).

We believe adopting the six claims-based measures above will have no effect on hospital burden because they do not require additional effort on the part of hospitals. We further believe adopting the Hospital Survey on Patient Safety Culture measure will have a minimal effect on hospital burden, as it involves filling out a one-time form to report on this measure for a given performance period. In total we estimate a burden of 15 minutes per hospital to complete other forms such as the ECE and Measure Exception form, and to report structural measures. The estimate of 15 minutes includes all previously finalized and newly required structural measures.

For the FY 2018 payment determination and subsequent years, we also are finalizing a modification of our proposal to require hospitals to report 16 electronic clinical quality measures to instead require hospitals to report a minimum of 4 electronic clinical quality measures. Under this modified policy, no NQS domain distribution will be required. We also are requiring that hospitals submit one quarter of data (either Q3 or Q4) for CY 2016/FY 2018 payment determination and subsequent years by February 28, 2017. We believe the finalized requirement will increase the burden associated with electronic clinical quality measure reporting because electronic reporting was previously voluntary. The total burden increase is estimated to be approximately 40 minutes per hospital to report 4 electronic clinical quality measures for one quarter. For hospitals choosing to submit more electronic clinical quality measures, the total burden increase for hospitals to report 16 electronic clinical quality measures would be approximately 2 hours and 40 minutes per hospital for one quarter.

We are finalizing our proposal to change the requirements for population and sampling such that hospitals will be required to submit population and sample size data only for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program. We believe this finalized proposal will result in a minimal decrease in burden as hospitals will not have to report population and sample size if they electronically report any of the measures that can be reported either as an electronic clinical quality measure or via chart-abstraction.

We also are finalizing our proposal to modify the existing processes for validation of chart-abstracted Hospital IQR Program data to remove one stratum. This modification will not affect hospital burden. For validation of chart-abstracted data for the FY 2018 payment determination and subsequent years, we require hospitals to provide 72 charts per hospital per year (with an average page length of 1,500), including 40 charts for HAI validation and 32 charts for clinical process of care validation, for a total of 108,000 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page (79 FR 50346) for a total per hospital cost of $12,960. For hospitals providing charts digitally via a re-writable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we will reimburse hospitals at a rate of 40 cents per disc. We do not believe

any additional burden is associated with data submitting this information via Web portal or PDF.

In addition to the activities described above, participation in the Hospital IQR Program requires hospitals to participate in a number of other activities, including: (1) Reviewing reports for claims-based measure sets; (2) completing HAI validation templates for CLABSI and CAUTI; (3) completing HAI validation templates for MRSA bacteremia and CDI; and (4) completing other forms and structural measures. The cumulative effects of these activities on facility burden are expected to be substantially similar to that stated for FY 2017. Considering the proposals finalized in this final rule, as well as our updated estimates for the number of records reported and the time associated with data reporting activities, we estimate a total burden of 2,289 hours per hospital and 7.6 million hours across approximately 3,300 hospitals participating in the Hospital IQR Program for the FY 2018 payment determination.

In general, however, we anticipate that, because of the new requirements we are finalizing for reporting for the FY 2018 payment determination, the number of hospitals not receiving the full annual percentage increase may be higher than average. Information is not available to determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for the FY 2018 payment determination. Historically, 100 hospitals, on average, of those participating in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year. The highest number of hospitals failing to meet program requirements was approximately 200 after the introduction of new NHSN reporting requirements. If the number of hospitals failing does increase because of the new requirements, we anticipate that, over the long run, this number will decline as hospitals gain more experience with these requirements.

Finally, under OMB Control Number 0938–1022, we estimated that the total burden for the FY 2017 payment determinations was 1,781 hours per hospital and 5.9 million hours across approximately 3,300 hospitals participating in the Hospital IQR Program. We estimate here that the total burden for the FY 2018 payment determination will increase to 2,289 hours per hospital and 7.6 million hours across approximately 3,300 hospitals due to the proposals discussed above and updates to the historical data used to determine the number of cases reported and time for reporting per measure set. The table below describes the hospital burden associated with the Hospital IQR Program requirements.

BURDEN IMPACT OF HOSPITAL IQR PROGRAM REQUIREMENTS FOR FY 2018 PAYMENT DETERMINATION

Hospital IQR Program requirement	Number of hospitals impacted	Burden per hospital for previously finalized	Burden per hospital for all requirements as adopted (continuing, removed, added)	Net change in burden per hospital
Chart-abstracted and structural measures, forms.	3,300	1,131 hours	906 hours	−225 hours.
Review reports for claims-based measures	3,300	4 hours	4 hours	0.
Electronic Clinical Quality Measure Reporting.	3,300	0 hours (electronic clinical quality measure reporting voluntary for FY 2017).	40 minutes	+40 minutes.
Validation templates	Up to 600	72 hours	72 hours	0.
Electronic Clinical Quality Measure validation test.	Up to 100	16 hours	0 hours (no test this year).	−16 hours.
Validation charts photocopying	Up to 600	$8,496	$12,960	+$4,464.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program for FY 2018

In section VIII.B. of the preamble of this final rule, we discuss our 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.

In section VIII.B.3. of the preamble of this final rule, we are finalizing our proposal that PCHs must submit data on three additional measures beginning with the FY 2018 program: (1) The CDC NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) the CDC NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and, (3) the CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel Measure (NQF #0431). In conjunction with our finalized proposal in section VIII.B.2. of the preamble of this final rule to remove the six SCIP measures from the PCHQR Program beginning with fourth quarter (Q4) 2015 discharges and for subsequent years, the PCHQR measure set will consist of 16 measures for the FY 2018 program.

The impact of the new requirements for the PCHQR Program is expected to be minimal overall because all 11 PCHs are already submitting quality measure data to the CDC NHSN and are familiar with this reporting process. Beginning with Q1 2013 events, PCHs have been submitting Central Line-associated Bloodstream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) data to the CDC NHSN (77 FR 53566). Similarly, beginning with Q1 2014 events, PCHs have been submitting Surgical Site Infections (SSI) data to the CDC NHSN (78 FR 50849). As a result, PCHs are familiar with the CDC NHSN IT infrastructure and programmatic operations. In addition to fostering transparency and facilitating public reporting, we believe our requirements uphold our goals in improving quality of care and achieving better health outcomes, which outweigh burden.

One expected effect of the PCHQR Program is to keep the public informed of the quality of care provided by PCHs. We will publicly display quality measure data collected under the PCHQR Program as required under the Act. These data will be displayed on the *Hospital Compare* Web site. The goals of making these data available to the public in a user-friendly and relevant format include, but are not limited to: (1) Allowing the public to compare PCHs in order to make informed health care decisions regarding care setting; and (2) providing information about current trends in health care. Furthermore, PCHs can use their own health care quality data for many purposes such as in risk management programs, healthcare associated infection prevention programs, and research and development activities, among others.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) for FY 2018

In section VIII.C.1. of the preamble of this final rule, we discuss the implementation of section 1886(m)(5) of the Act, which was added by section 3004(a) of the Affordable Care Act. Section 1886(m)(5) of the Act provides that, for rate year 2014 and each subsequent year, any LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) and (F) of the Act shall receive a two (2) percentage point reduction to the annual update to the standard Federal rate for discharges for the hospital during the applicable fiscal year.

In the FY 2015 IPPS/LTCH PPS final rule (76 FR 50443 through 50445), we estimated

that only a few LTCHs will not receive the full annual percentage increase in any fiscal year as a result of failure to submit data under the LTCH QRP. There are approximately 442 LTCHs currently reporting quality data to CMS. At the time that this analysis was prepared, 47, or approximately 10 percent, of these LTCHs did not receive the full annual percentage increase for the FY 2015 annual payment update determination. Information is not available to determine the precise number of LTCHs that will not meet the requirements to receive the full annual percentage increase for the FY 2016 payment determination.

We believe that a majority of LTCHs will continue to collect and submit data for the FY 2017 payment determination and subsequent years because they will continue to view the LTCH QRP as an important step in improving the quality of care patients receive in the LTCHs. We believe that the burden associated with the LTCH QRP is the time and effort associated with data collection.

In this FY 2016 IPPS/LTCH PPS final rule, we are retaining 12 previously finalized measures, 2 of which we are adopting in order to establish their use as cross-setting measures that satisfy the required addition of quality measures under the domains of skin integrity and incidence of major falls, as mandated by the section 1899B of the Act: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). We are adopting a third previously finalized measure, All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), in order to establish the newly NQF-endorsed status of this measure. Finally, we are finalizing an Application of Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015), which satisfies the addition of a quality measure under the third initially required domain of functional status, cognitive function, and changes in function and cognitive function, as mandated by section 1899B of the Act.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445) we discussed burden estimates that were inclusive of the 12 previously finalized measures we are retaining in this final rule. We previously estimated the total cost for all 12 quality measures to be $17,410 per LTCH annually, or $7,695,423 for all LTCHs annually (79 FR 50443 through 50445); or $2,992,384 for all quality measures reported via the CDC's NHSN; and $4,703,039 for all quality measures reported to CMS using the LTCH CARE Data Set version 2.01. For a list of the 12 previously finalized measures included in the above burden estimate, we refer readers to the FY 2015 IPPS/LTCH PPS final rule.

The burden calculation discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445) accounts for any burden associated with newly finalized measures in this FY 2016 IPPS/LTCH PPS final rule. The measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), is currently being reported by LTCHs using version 2.01 of the LTCH CARE Data Set, which has burden approval under OMB control number 0938–1163. The burden associated with the application of the measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), is discussed at length in the FY 2015 IPPS/LTCH PPS final rule, and is included in the above total annual burden figures in that rule, as well as listed above.

The measure, All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), is calculated based on CMS FFS claims data, and therefore does not have any associated data reporting burden for LTCH providers.

The new quality measure we are finalizing for inclusion in the LTCH QRP, the cross-setting functional status process measure: an Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function, is not specifically discussed in the FY 2015 IPPS/LTCH PPS final rule. However, the data elements used to report this quality measure to CMS are included in that discussion and burden estimate in that final rule, because we are finalizing our proposal to use a subset of the same data elements that are used to report the previously finalized measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function, which is included in that burden estimate. Therefore, the addition of this quality measure to the LTCH QRP does not increase burden on LTCHs.

Currently, LTCHs use two separate data collection mechanisms to report quality data to CMS: The CDC's NHSN, which is used to report all Healthcare Associated Infection (HAI) and vaccination data (used to calculate CAUTI, CLABSI, MRSA, CDI, VAE, and Healthcare Personnel Influenza vaccination measures); and the Quality Improvement and Evaluation System Assessment Submission and Processing (QIES ASAP) system, which is used by LTCHs to report quality data via the LTCH CARE Data Set.

The data collection burden associated with the reporting of the quality measures (HAI and vaccination) reported via the CDC's NHSN is discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445). However, we note that these measures are stewarded by the CDC, and the reporting burden is approved under OMB control number 0920–0666.

The remaining quality measures are reported to CMS by LTCHs using the LTCH CARE Data Set. Currently, LTCHs are using version 2.01 of the LTCH CARE Data Set (approved under OMB control number 0938–1163) which includes data elements related to two quality measures: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678) and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680).

We have developed a subsequent iteration of the LTCH CARE Data Set (version 3.00), which will also include data elements for the three quality measures we previously finalized in the FY 2015 IPPS/LTCH PPS final rule: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674); Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015); and Functional Status Outcome Measure: Change in Mobility Among LTCH Patients Requiring Ventilator Support (NQF #2632; endorsed on 07/23/2015). We refer readers to section X.B.9. of the preamble of this final rule for a discussion of the additional data elements in version 3.00 of the LTCH CARE Data Set.

Version 3.00 of the LTCH CARE Data Set will also be used to report the newly finalized cross-setting functional status process measure, an Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015). However, the data items that will inform this measure are a subset of the data elements currently used to report the LTCH-specific measure, Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on 07/23/2015). Therefore, this measure will not add any data collection burden beyond that discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445), in which NQF #2631 was finalized.

We discussed the LTCH burden related to the submission using the LTCH CARE Data Set version 3.00 in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445), and this burden is included in the total annual burden noted in that final rule, which is $17,410 per LTCH annually, or $7,695,423 for all LTCHs annually. We believe that this estimate remains unchanged as a result of the LTCH QRP proposals we are finalizing in this final rule. We received several comments on these proposals, which we summarize and respond to below.

Comment: One commenter recommended that CMS modify the LTCH CARE Data Set to ensure consistent and necessary data will appropriately and accurately populate the required quality measures for the implementation of the IMPACT Act of 2014 as well as ongoing implementation of the LTCH QRP.

Response: We appreciate and agree with the commenter's recommendations. As evidenced from our efforts to develop and successfully implement the LTCH CARE Data Set version 1.01 to support the implementation of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure starting on October 1, 2012, and our subsequent revisions and implementation of LTCH CARE Data Set version 2.01 starting on July 1, 2014 to support the implementation of an additional quality measure the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), we have developed the LTCH CARE Data Set version 3.00 to support the implementation

of additional quality measures as part of the LTCH QRP starting on April 1, 2016. We intend to continue to further revise and develop the LTCH CARE Data Set in order to support CMS efforts to successfully implement quality measures we adopt for the LTCH QRP through future rulemaking. At this time, we believe the LTCH CARE Data Set version 3.00 includes the necessary items required to support data collection to appropriately and accurately capture patient-level data for each of the quality measures adopted for April 1, 2016 implementation, for the LTCH QRP.

Comment: One commenter suggested combining several items in Section GG of the LTCH CARE Data Set version 3.00. Specifically, the commenter suggested combining the three walking items and the two wheelchair items.

Response: We appreciate the commenter's review of the LTCH CARE Data Set. Based on our analyses of the PAC PRD data and our feedback from the PAC PRD participants, we believe it is important to document the walking and wheeling distances as well as assistance needed for the activities of walking and wheelchair mobility. Therefore, we will not make changes to the LTCH CARE Data Set version 3.00 in response to this suggestion.

Comment: Several commenters were concerned that, in the process of trying to limit some of the data fields that made up the LTCH CARE Data Set, CMS has inappropriately collapsed response categories, such as in the section focused on Active Diagnoses, Comorbidities and Co-Existing Conditions. For example, the commenters asked for clarification of Severe Cancers and Opportunistic Infections as they considered the term to be subjective and could lead to inconsistent reporting across facilities.

Response: We appreciate the commenters' review of the LTCH CARE Data Set. We will provide detailed instructions in the LTCH QRP Manual version 3.0, including providing examples of severe cancers and opportunistic infections. The diagnosis groupings that we include on the LTCH CARE Data Set version 3.00 are the labels and definitions from the Hierarchical Condition Categories (HCCs), and some HCCs were further merged based on sample size requirements and the regression analysis results. Severe cancers can include, but are not limited to, cancer of stomach; cancer of liver; cancer of pancreas; cancer of trachea, bronchus, lung, and pleura; and multiple myeloma. Opportunistic infections include, but are not limited to, cytomegaloviral disease, including pneumonia; candidiasis of lung, esophagus, or disseminated; opportunistic mycoses (aspergillosis, cryptococcosis, zygomycosis, etc.); and pneumocystis pneumonia. We understand the importance of education and have worked in the past with public outreach, including training sessions, training manuals, Webinars, open door forums, help desk support and a Web site that hosts training information (*http://www.youtube.com/user/CMSHHSgov*). We plan to conduct such activities for the new items.

Comment: A few commenters suggested that, for patients who are in a coma/persistent vegetative state, the LTCH CARE Data Set include a skip pattern that allows the clinician to skip the Confusion Assessment Method (CAM©) items.

Response: We appreciate the commenters' suggestion to add a skip pattern that would reduce burden. We have taken this suggestion into consideration and determined that skipping the CAM© for patients in a coma is appropriate and therefore, we will implement this skip pattern.

Comment: One commenter noted that many of the data elements in the LTCH CARE Data Set will engender codes indicating ''Not applicable'' and ''Activity did not occur due to medical condition or safety concerns.''

Response: We agree with the commenter and are aware that for several of the data elements in the LTCH CARE Data Set, codes ''Not applicable'' and ''Activity did not occur due to medical condition or safety concerns'' may be appropriate. We anticipate that in the instances when a patient is unable to respond and family members are not able to provide the information, these codes would be appropriate. We invite readers to review the data submission specifications for information on specific codes (including ''Not applicable'' and ''Activity did not occur due to medical condition or safety concerns'') allowed for each data element of the LTCH CARE Data Set version 3.00, available for download on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html*.

Comment: One commenter noted that the CARE Item Set would take 60 minutes to complete in the LTCH setting although Pilot 2 of the PAC PRD (available at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html*) stated that, despite the request for time estimates at the end of each CARE tool domain, ''The amount of time taken to fill out the form was completed for up to half the records for some sections, and not at all for others.''

Response: We thank the commenter for reviewing and drawing upon the PAC PRD reports to inform their concern and feedback on burden estimates. We would like to clarify that the burden associated with the CARE Tool (which was used in PAC PRD) is not directly applicable to the LTCH CARE Data Set (which has been in use as part of LTCH QRP since October 1, 2012). Specifically, we are clarifying that we pay careful attention to and make every attempt to reduce LTCH burden for compliance with the LTCH QRP (including completion of LTCH CARE Data Set to submit data on quality measures adopted for the LTCH QRP). This is among several reasons why we have taken an incremental approach to develop and implement the LTCH CARE Data Set to include only those items that support data collection for quality measures adopted for the LTCH QRP and why we have not implemented the CARE Tool in its entirety.

Further, we are clarifying that there is no new burden associated with the additions to Section GG of the LTCH CARE Data Set, since the measures adopted through this final rule will utilize data elements that are collected under the LTCH CARE Data Set version 3.00. These data elements were previously finalized through rulemaking in order to inform quality measures that were previously finalized, and for which data collection will begin on April 1, 2016.

After consideration of the public comments we received, we are finalizing our estimates of the burden associated with the use of LTCH CARE Data Set version 3.00 for implementation starting April 1, 2016. Further, we are finalizing our use of CDC's burden estimates for using NHSN for data collection and submission of NHSN-based quality measures.

II. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

III. Overall Conclusion

1. Acute Care Hospitals

Table I of section I.G. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows an overall increase of 0.4 percent in operating payments. As discussed in section I.G. of this Appendix, we estimate that operating payments will increase by approximately $378 million in FY 2016 relative to FY 2015. However, when we account for the impact of the changes in Medicare DSH payments and the impact of the new additional payments based on uncompensated care in accordance with section 3133 of the Affordable Care Act, based on estimates provided by the CMS Office of the Actuary, consistent with our policy discussed in section IV.D. of the preamble of this final rule, we estimate that operating payments will increase by approximately $75 million relative to FY 2015. We currently estimate that the changes in new technology add-on payments for FY 2016 will increase spending by approximately $9.5 million due to the expiration of three new technology add-on payments and the additional approval of two new technology add-on payments. This estimate, combined with our estimated increase in FY 2016 operating payment of $75 million, results in an estimated increase of approximately $85 million for FY 2016. We estimate that hospitals will experience a 2.3 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there will be a $187 million increase in capital payments in FY 2016 compared to FY 2015. The cumulative operating and capital payments will result in a net increase of approximately $272 million to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience a decrease in estimated payments per discharge in FY 2016. In the impact analysis, we are using the rates, factors, and policies presented in this final rule, including updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2016. Accordingly, based on the best available data for the 419 LTCHs in our database, we estimate that FY 2016 LTCH PPS payments will decrease approximately $250 million relative to FY 2015 as a result of the payment rates and factors presented in this final rule.

IV. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table V below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final 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 changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

The cost to the Federal Government associated with the policies in this final rule are estimated at $272 million.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMIATED EXPENDITURES UNDER THE IPPS FROM FY 2015 TO FY 2016

Category	Transfers
Annualized Monetized Transfers.	−$272 million.
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 payment rates and factors presented in this final rule under the LTCH PPS, is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2016 relative to FY 2015 of approximately $250 million based on the data for 419 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table VI below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final 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 payment rates and factors and other provisions presented in this final rule based on the data for the 419 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

The savings to the Federal Government associated with the policies for LTCHs in this final rule are estimated at $250 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2015 LTCH PPS TO THE FY 2016 LTCH PPS

Category	Transfers
Annualized Monetized Transfers.	−$250 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

V. 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 Web site 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 final rule relating to acute care hospitals would have a significant impact on small entities as explained in this Appendix. 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 we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this final rule constitutes our regulatory flexibility analysis. In FY 2016 IPPS/LTCH PPS proposed rule, we solicited public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we received and our responses are presented throughout this final rule.

VI. 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 603 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.)

VII. 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 2015, that threshold level is approximately $144 million. This final rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

VIII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this final 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, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the Puerto Rico-specific standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we have 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 2016, we plan to include 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 2016

A. FY 2016 Inpatient Hospital Update

As discussed in section IV.A. of the preamble to this final rule, for FY 2016, 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 66 2/3 percent reduction to three-fourths 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 0.2 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 2016 adjustment of 0.2 percentage point may result in the applicable percentage increase being less than zero.

In the FY 2016 IPPS/LTCH PPS proposed rule, based on the most recent data available at that time, in accordance with section 1886(b)(3)(B) of the Act, we proposed to establish the FY 2016 market basket update used to determine the applicable percentage increase for the IPPS based on IHS Global Insight, Inc.'s (IGI's) first quarter 2015 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2014, which was estimated to be 2.7 percent. Based on the most recent data available for this FY 2016 final rule, in accordance with section 1886(b)(3)(B) of the Act, we are establishing the FY 2016 market basket update used to determine the applicable percentage increase for the IPPS based on IHS Global Insight, Inc.'s (IGI's) second quarter 2015 forecast of the FY 2010-based IPPS market basket rate-of-increase, which is estimated to be 2.4 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.A. of the preamble of the FY 2016 IPPS/LTCH PPS proposed rule, we proposed a multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2016) of 0.6 percent. Therefore, based on IGI's first quarter 2015 forecast of the FY 2010-based IPPS market basket, 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 presented in the proposed rule four possible applicable percentage increases that could be applied to the standardized amount. Based on the most recent data available for this FY 2016 IPPS/LTCH PPS final rule, 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.A. of the preamble of this final rule, we are establishing a MFP adjustment (the 10-year moving average of MFP for the period ending FY 2016) of 0.5 percentage point.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, as discussed in section IV.A. of the preamble of this final rule, we are establishing the applicable percentages increases for the FY 2016 updates based on IGI's second quarter 2015 forecast of the FY 2010-based IPPS market basket, 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, as outlined in the table below.

FY 2016	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
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.6	−0.6
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−1.2	0.0	−1.2
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Applicable Percentage Increase Applied to Standardized Amount	1.7	0.5	1.1	−0.1

B. Update for SCHs and MDHs for FY 2016

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2016 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.L. of the preamble of this final 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).

As mentioned above, 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 establishing the same four applicable percentage increases in the table above for the hospital-specific rate applicable to SCHs and MDHs.

C. FY 2016 Puerto Rico Hospital Update

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are making an applicable percentage increase to the Puerto

Rico-specific standardized amount of 1.7 percent.

D. Update for Hospitals Excluded From the IPPS for FY 2016

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. We are applying the FY 2016 percentage increase in the IPPS operating market basket to the target amount 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 this final rule, the current estimate of the FY 2016 IPPS operating market basket percentage increase is 2.4 percent.

E. Update for LTCHs for FY 2016

As discussed in section V.A. of the Addendum to this final rule, we are establishing an update to the LTCH PPS standard Federal rate for FY 2016 based on the full LTCH PPS market basket increase estimate (for the proposed rule, we estimated this to be 2.7 percent; for this final rule, we estimate this to be 2.4 percent), subject to an adjustment based on changes in economy-wide productivity and an additional reduction required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. In accordance with the LTCH QRP under section 1886(m)(5) of the Act, we are reducing 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. The MFP adjustment described under section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.5 percent for FY 2016. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2016 be reduced by the ''other adjustment'' at section 1886(m)(4)(E) of the Act, which is 0.2 percentage point. Therefore, based on more recent data from the proposed rule, that is, the IGI's second quarter 2015 forecast of the FY 2016 LTCH PPS market basket increase, we are establishing an annual update to the LTCH PPS standard Federal rate of 1.7 percent (that is, the current FY 2016 estimate of the market basket rate-of-increase of 2.4 percent less an adjustment of 0.5 percentage point for MFP and less 0.2 percentage point). Accordingly, we are applying an update factor of 1.7 percent in determining the LTCH PPS standard Federal rate for FY 2016. For LTCHs that fail to submit quality data for FY 2016, we are applying an annual update to the LTCH PPS standard Federal rate of –0.3 percent (that is, the annual update for FY 2016 of 1.7 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 an update factor of −0.3 percent in determining the LTCH PPS standard Federal rate for FY 2016.

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to 3.25 percent for FY 2016. 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. For the Puerto Rico-specific standardized amount, we are recommending an update of 1.7 percent.

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, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa of 2.4 percent.

For FY 2016, consistent with policy set forth in section VII. of the preamble of this final rule, for LTCHs that submit quality data, we are recommending an update of 1.7 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2016, we are applying an annual update to the LTCH PPS standard Federal rate of −0.3 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2015 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 equal to 3.25 percent concurrent with changes to the outpatient prospective payment system and with initiating change to the LTCH PPS. We refer the reader to the March 2015 MedPAC report, which is available on the Web site at *http://www.medpac.gov* for a complete discussion on this recommendation. MedPAC expects Medicare margins to remain low in 2015. At the same time, MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care. However, under current law, payment margins are projected to decline which could result in negative Medicare margins industry wide. Specifically, MedPAC noted several current law policy changes are scheduled to reduce payments in FY 2015 and FY 2016. Because of these changes and reduced payments, MedPAC asserted that an update of 3.25 percent in the base payment is warranted. MedPAC maintains that Medicare payment rates should be determined by analysis of payment adequacy rather than an across-the-board sequester reduction. Therefore, MedPAC recommended that hospitals receive base payment rates that are 3.25 percent higher than the FY 2015 base payment rates, and there should be no sequester adjustment. However, MedPAC concluded that if the Congress increases hospital payments by reinstating expiring special payments, the full 3.25 percent update would not be warranted.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 3.25 percent, for FY 2016, as discussed above, section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the requirements for the FY 2016 applicable percentage increase. Therefore, we are applying an applicable percentage increase for FY 2016 of 1.7 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with these statutory requirements.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for *Brickellia mosieri* (Florida Brickell-bush) and *Linum carteri* var. *carteri* (Carter's Small-flowered Flax); Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2013–0108: 4500030114]

RIN 1018–AZ64

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Brickellia mosieri (Florida Brickell-bush) and Linum carteri var. carteri (Carter's Small-flowered Flax)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), designate critical habitat for *Brickellia mosieri* (Florida brickell-bush) and *Linum carteri* var. *carteri* (Carter's small-flowered flax) under the Endangered Species Act of 1973, as amended (Act). We designate as critical habitat approximately 1,062 hectares (ha) (2,624 acres (ac)) for *B. mosieri* and approximately 1,072 ha (2,649 ac) for *L. c.* var. *carteri.* The critical habitat areas for these plants, located entirely in Miami-Dade County, Florida, largely overlap, for a combined total of approximately 1,095 ha (2,706 ac). Critical habitat for both plants includes both occupied and unoccupied habitat. The Service determined that the unoccupied units are essential for the conservation of the plants, to provide for the necessary expansion of current *Brickellia mosieri* and *Linum carteri* var. *carteri* populations, and for reestablishment of populations into areas where these plants previously occurred. The effect of this regulation is to extend the Act's protections to these plants' critical habitats.

DATES: This rule is effective on September 16, 2015.

ADDRESSES: This final rule is available on the internet at *http://www.regulations.gov* and from the South Florida Ecological Services Field Office. Comments and materials we received, as well as some supporting documentation we used in preparing this final rule, are available for public inspection at *http://www.regulations.gov.* All of the comments, materials, and documentation that we considered in this rulemaking are available by appointment, during normal business hours at: U.S. Fish and Wildlife Service, South Florida Ecological Services Field Office, 1339 20th Street, Vero Beach, FL 32960; by telephone 772–562–3909; or by facsimile 772–562–4288. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

The coordinates or plot points or both from which the maps were generated are included in the administrative record for this critical habitat designation and are available at *http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0108, and at the South Florida Ecological Services Field Office (*http://www.fws.gov/verobeach/*) (see **FOR FURTHER INFORMATION CONTACT**). Any additional tools or supporting information that we developed for this critical habitat designation will also be available at the Fish and Wildlife Service Web site and Field Office addresses provided above, and at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Dana Hartley, Endangered Species Supervisor, U.S. Fish and Wildlife Service, South Florida Ecological Services Field Office, 1339 20th Street, Vero Beach, FL 32960; by telephone 772–562–3909; or by facsimile 772–562–4288. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, when we list a species as endangered or threatened, we must designate critical habitat, to the maximum extent prudent and determinable. Designations of critical habitat can only be completed by issuing a rule.

We listed *Brickellia mosieri* and *Linum carteri* var. *carteri* as endangered species on September 4, 2014 (79 FR 52567). On October 3, 2013, we published in the **Federal Register** a proposed critical habitat designation for *B. mosieri* and *L. c.* var. *carteri* (78 FR 61293). Section 4(b)(2) of the Act states that the Secretary shall designate critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat.

The critical habitat areas we are designating in this rule constitute our current best assessment of the areas that meet the definition of critical habitat for *Brickellia mosieri* and *Linum carteri* var. *carteri.* Here we are designating approximately 1,062 ha (2,624 ac) as critical habitat for *Brickellia mosieri* and approximately 1,072 ha (2,649 ac) for *Linum carteri* var. *carteri.* The critical habitat areas for these plants, located entirely in Miami-Dade County, Florida, largely overlap, for a combined total of approximately 1,095 ha (2,706 ac). Critical habitat for both plants includes both occupied and unoccupied habitat. The Service determined that the unoccupied units are essential for the conservation of the plants, to provide for the necessary expansion of current *Brickellia mosieri* and *Linum carteri* var. *carteri* populations, and for reestablishment of populations into areas where these plants previously occurred.

This rule consists of: A final rule designating critical habitat for *Brickellia mosieri* and *Linum carteri* var. *carteri* under the Act.

We have prepared an economic analysis of the designation of critical habitat. We have prepared an analysis of the economic impacts of the critical habitat designations and related factors. We announced the availability of the draft economic analysis (DEA) in the **Federal Register** on July 15, 2014 (79 FR 41211), allowing the public to provide comments on our analysis. We have incorporated the comments and have completed the economic analysis concurrently with this final designation.

Peer review and public comment. We sought comments from independent specialists to ensure that our designation is based on scientifically sound data and analyses. We obtained opinions from five knowledgeable individuals with scientific expertise to review our technical assumptions and analysis, and whether or not we had used the best available information. These peer reviewers generally concurred with our methods and conclusions, and provided additional information and suggestions to improve this final rule. Information we received from peer review is incorporated in this final revised designation. We also considered all comments and information received from the public during the comment periods.

Previous Federal Actions

For more information on previous Federal actions concerning *Brickellia mosieri* and *Linum carteri* var. *carteri,* refer to the proposed rules published in the **Federal Register** on October 3, 2013 (78 FR 61273 and 78 FR 61293), and the final listing rule published in the **Federal Register** on September 4, 2014 (79 FR 52567), which are available online at *http://www.regulations.gov* or from the South Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Summary of Comments and Recommendations

We requested written comments from the public on the proposed designation of critical habitat for *Brickellia mosieri* and *Linum carteri* var. *carteri* during two comment periods. The first comment period opened with the publication of the proposed rule (78 FR 61293) on October 3, 2013, and closed on December 2, 2013. We also requested comments on the proposed critical habitat designation and associated draft economic analysis during a comment period that opened July 15, 2014, and closed on August 14, 2014 (79 FR 41211). We also contacted appropriate Federal, State, and local agencies; scientific organizations; and other interested parties and invited them to comment on the proposed rule and draft economic analysis during these comment periods.

During the first comment period, we received 10 comment letters directly addressing the proposed critical habitat designation. During the second comment period, we received six comment letters addressing the proposed critical habitat designation. We did not receive any requests for a public hearing during either comment period. All substantive information provided during the comment periods specifically relating to the proposed designation either has been incorporated directly into this final designation or is addressed below.

Peer Review

In accordance with our peer review policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), we solicited expert opinions from six knowledgeable individuals with scientific expertise, that included familiarity with *Brickellia mosieri* and *Linum carteri* var. *carteri* and/or their habitat, biological needs, and threats; the geographical region of South Florida in which these plants occur; and conservation biology principles. We received responses from five of the peer reviewers.

We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding critical habitat for *Brickellia mosieri* and *Linum carteri* var. *carteri.* The peer reviewers generally concurred with our methods and conclusions, and provided additional information and suggestions to improve the final critical habitat rule. Peer reviewer comments are addressed in the following summary and incorporated into the final rule as appropriate.

(1) *Comment:* One peer reviewer requested that additional information be provided regarding the source of ownership data and conservation lands. This reviewer also requested that ownership data and conservation land boundaries be referenced on the critical habitat maps or additional maps.

Our Response: Ownership of proposed critical habitat areas in the proposed rule was determined using geographic information system (GIS) data consisting of Miami-Dade County parcel layer (August 2008 version) and the Florida Natural Areas Inventory (FNAI) Florida Managed Areas layer (March 2009 version). Ownership of critical habitat areas in this final rule was determined using updated GIS data consisting of Miami-Dade County parcel layer (July 2013 version) and FNAI Florida Managed Areas layer (March 2014 version); this information has been incorporated into Tables 1 and 2 in the Final Critical Habitat Designation section, below. With regard to the inclusion of ownership data and conservation area boundaries on critical habitat maps, we prepare these maps under the parameters for publication within the Code of Federal Regulations. While we attempted in the proposed rule to provide detail such as select area names to better show the location of critical habitat areas along the Miami Rock Ridge, the scale of the maps prevented all conservation areas or ownership data from being depicted. This is still the case for maps showing the final critical habitat designation, which retained the same scale as maps in the proposed rule. More detailed information is available at the South Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

(2) *Comment:* One peer reviewer suggested that the FNAI Florida Element Occurrence (FLEO) data for the pine rockland natural community and rare plants, animals, and invertebrates could have been used in our designation of critical habitat units. The reviewer also commented on the lack of map references to these and other spatial occurrence data (from Fairchild Tropical Botanic Garden (FTBG), the Institute for Regional Conservation (IRC), and other sources), while allowing that the latter were well referenced in the proposed rule.

Our Response: We appreciate the reviewer's comment. We did review the FLEO data for rare pine rockland species as part of our anlaysis, and have added text reflecting this under the *Criteria Used To Identify Critical Habitat* section, below. We were not aware of available FLEO data for the pine rockland natural community. We have since inquired with FNAI regarding these data, and have found out that the information available is only for some, not all, pine rocklands on the Miami Rock Ridge, and that detailed data (*e.g.,* habitat condition, species occurrences) for most areas are at least 10 years old. Thus, we believe that the information we used in our critical habitat analysis (specifically, recent aerial photography and the feedback of experts familiar with on-the-ground conditions) is more appropriate to a current assessment of habitat conditions than the FLEO pine rockland data, and constitutes the best available scientific and commercial information. Please refer to our response to *Comment (1),* above, regarding the inclusion of additional information on critical habitat maps.

(3) *Comment:* One peer reviewer recommended including the fire-suppressed pine rockland habitat located between Ross and Castellow Hammocks in *Brickellia mosieri'*s designated critical habitat, based on it being the type locality for the plant.

Our Response: In our analysis of proposed critical habitat, some areas of former pine rockland habitat were considered too severely fire suppressed (*i.e.,* having extremely dense canopy cover, based on our assessment of aerial photography) such that they are now unsuitable habitat for *Brickellia mosieri,* and unlikely to be able to be restored. These areas were not delineated as pine rocklands in our critical habitat analysis, and thus were not included in the consequence matrix used to identify unoccupied habitat for designation. This included the severely fire-suppressed pine rockland between Ross and Castellow Hammocks. Our assessment has been confirmed by a species expert who conducts monitoring in the area and is familiar with current habitat conditions. Thus, we believe that the subject area is not appropriate for inclusion in the critical habitat designation at this time.

(4) *Comment:* One peer reviewer noted that our methodology and choice of critical habitat patches appear very reasonable, but suggested supporting future critical habitat designations with quantitative analyses, such as those that would provide the quantitative contribution of each patch to network connectivity.

Our Response: We appreciate the reviewer's comment. In our analysis for the proposed rule, we evaluated connectivity of each habitat patch using two criteria: The number of other pine rockland habitat patches within 2 kilometers (km) (1.2 miles (mi)), and the distance to the nearest pine rockland

patch within a 2-km (1.2-mi) radius (where a score of ''0'' signaled adjacent patches). In this quantitative ranking, scores for both of these criteria were calculated in GIS using the pine rockland habitat layer we previously delineated as described in the *Criteria Used To Identify Critical Habitat* section, below. By applying these criteria, given areas of equal habitat quality, size, and surrounding landscape composition, those patches having more and closer neighbors (*i.e.,* other pine rockland patches) would be ranked higher in our evaluation. The intent of these criteria was to maximize patch connectivity within each geographic area. We believe this was the best approach for delineating the critical habitat for these two plants, but appreciate that the reviewer's suggested evaluation approach may be useful in developing a consequence matrix in future critical habitat designations, where necessary and appropriate.

(5) *Comment:* One peer reviewer suggested adding many of the mowed fields within the U.S. Coast Guard (USCG) and Miami Zoo properties to the designated critical habitat in Unit 4 (now, Units BM4 and LCC4). The reviewer stated that these lack a pine canopy and shrub layer, but support a high diversity of pine rockland species, including State-listed and federally listed plants, and noted that similar mowed areas likely occur in other portions of the Richmond Pinelands. We received a similar comment, concerning a mowed area on the USCG property, during the second public comment period (see response to Comment (10) below).

Our Response: We thank the reviewer for this comment. We acknowledge that mown areas having pine rockland substrate (*i.e.,* cleared pine rocklands) support some imperiled pine rockland plants, including *Linum carteri* var. *carteri.* However, while cleared areas currently support occurrences of *L. c.* var. *carteri,* scientific data are lacking with regard to the reason for this—whether it be a requirement related to very high light conditions, disturbed substrate, or a combination of these or other factors not yet identified. For the long-term conservation of these plants, we consider habitats having a completely open canopy (*i.e.,* cleared pine rocklands) to be less preferred than intact pine rockland having suitable canopy cover. Accordingly, cleared areas scored lower quantitatively for onsite habitat quality than intact pine rockland, and thus had a lower overall ranking in our consequence matrix, which we used to evaluate the conservation quality of unoccupied habitat (discussed in the *Criteria Used To Identify Critical Habitat* section, below). Mown fields within USCG and Miami Zoo lands, and surrounding land in the Richmond Pinelands, were included in our evaluation, but did not rank high enough (*i.e.,* conservation quality ranking was less than 0.50) for inclusion in the critical habitat designation. Based on our assessment, we do not believe these areas are essential to the plant's conservation at this time. However, we are actively communicating with both USCG and Miami-Dade County, and are supportive of conservation measures that would benefit *L. c.* var. *carteri* on these lands (*e.g.,* optimizing mowing regime).

(6) *Comment:* One peer reviewer provided additional information related to cultivated plantings of *Brickellia mosieri,* citing an observation of larger, more vigorous individuals than their wild counterparts, and the potential for plantings of both *B. mosieri* and *Linum carteri* var. *carteri* to provide a continual input of propagules that may successfully colonize other pine rockland areas.

Our Response: We thank the reviewer for this additional information, and support such planting programs (*e.g.,* FTBG's Connect to Protect Network) to aid in the recovery of these plants.

Comments From States

Section 4(i) of the Act (16 U.S.C. 1531 *et seq.*) states, ''the Secretary shall submit to the State agency a written justification for [her] failure to adopt regulations consistent with the agency's comments or petition.'' The two plants only occur in Florida, and we received no comments from the State of Florida regarding the critical habitat proposal. We note, however, that one peer reviewer was from the Florida Forest Service, Florida Department of Agriculture and Consumer Services; those comments are addressed above.

Public Comments

(7) *Comment:* One commenter stated that there is no reason why a population of *Brickellia mosieri* could not be supported at Tropical Park (in the vicinity of Unit BM1).

Our Response: We thank the reviewer for this comment. In our evaluation of unoccupied habitat, we used the best available scientific data to establish a minimum habitat size that would likely support a sustaining population of *Brickellia mosieri.* Based on expert opinion, we excluded unoccupied patches below 2 ha (5 ac) for *B. mosieri* (see ''Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring,'' in the proposed critical habitat rule published in the **Federal Register** on October 3, 2013 (78 FR 61293)). The pine rockland habitat patch at Tropical Park (unoccupied) is approximately 1.7 ha (4.3 ac), and thus was not included in the consequence matrix for *B. mosieri.* Although some sites occupied by *B. mosieri* are less than 2 ha (5 ac) in size, it is not known whether these populations are sustainable in the long term. Thus, we believe that our minimum size threshold for unoccupied habitat is a conservative estimate, and that the methodology we used to determine proposed critical habitat supports the identification of pine rockland habitat patches with the highest conservation quality.

(8) *Comment:* Two commenters suggested revising the criteria used to evaluate onsite habitat quality in the consequence matrix, which was used to score and rank unoccupied pine rockland habitat patches in our critical habitat analysis. Both commenters stated that it would be more appropriate (especially for *Linum carteri* var. *carteri*) for pine rockland with a canopy openness greater than 50 percent to score higher than pine rockland with 25–50 percent canopy openness.

Our Response: We appreciate the comment and acknowledge that *Linum carteri* var. *carteri* responds favorably to high light conditions, including disturbed pine rocklands with canopy openness near 100 percent. Such cleared areas currently support occurrences of *L. c.* var. *carteri,* but scientific data are lacking with regard to the reason for this—whether it be a requirement related to very high light conditions, disturbed substrate, or a combination of these or other factors not yet identified. The criteria used to evaluate onsite habitat quality reflect our belief that habitats having a completely open canopy (*i.e.,* cleared pine rocklands) are less preferred than intact pine rockland having suitable canopy cover for the long-term conservation of these plants. However, to investigate whether and how the suggested change to scoring would impact the set of unoccupied habitat patches having an overall score greater than 0.50, we conducted a test revision of the consequence matrix for *L. c.* var. *carteri.* Scoring of canopy cover was adjusted as follows: If canopy was estimated to be 50 to 75 percent open, that patch received the highest possible score for that criteria (*i.e.,* a ''4''; original score for these patches was a ''3''); patches with a canopy estimated to be greater than 75 percent open received a score of ''3'' (original score was a ''2''); patches with a canopy estimated to be

25 to 50 percent open received a score of ''2'' (original score was a ''4''); and patches with a canopy estimated to be less than 25 percent open (*e.g.,* having a closed canopy due to inadequate fire management and extensive cover by nonnative invasive plants) received the lowest possible score (''1''; unchanged from original scoring). We then compared these test patch rankings to rankings under the original scoring scheme. All habitat patches for *L. c.* var. *carteri* in the original matrix having a total score greater than 0.63 were still in the revised set. Based on total score greater than 0.50 (our chosen cut-off for conservation quality as discussed in the *Criteria Used To Identify Critical Habitat* section, below), the revised set of unoccupied habitat patches for *L. c.* var. *carteri* included 3 new patches, but did not include 28 previously included patches (compared to proposed critical habitat in the proposed rule published in the **Federal Register** on October 3, 2013 (78 FR 61293)). The net area difference, based on the revised versus original matrix, was approximately 101 ha (250 ac) less than the proposed critical habitat. We also evaluated the revised set of habitat patches spatially, and determined that the revised polygon set had reduced connectivity, particularly in the area between the U.S. Department of Agriculture's Chapman Field (on the coast) and more interior habitat to the southwest. Lastly, we evaluated aerial photography of the individual polygons that would be added, and do not believe that they represent quality habitat—as pine rockland habitat in general, or for *L. c.* var. *carteri* specifically. Evaluation of aerial photography of the individual polygons that would be deleted indicates that at least some of these areas represent high-quality pine rockland habitat, including areas that could be open enough for *L. c.* var. *carteri.*

Based on our test revision, it seems apparent that a lower cut-off value for conservation quality would be needed to capture these high-quality areas and achieve adequate connectivity if the revised scoring was used. Therefore, we do not believe that the suggested scoring revision would result in a more appropriate set of habitat patches for *L. c.* var. *carteri,* and thus have not made any changes to the consequence matrix. One reason that the revised scoring did not result in the anticipated improvement to proposed critical habitat for *L. c.* var. *carteri* may be due to the way in which we scored patch canopy cover—that is, the entire polygon received a single score for canopy cover, although in many cases canopy cover is not distributed evenly through a habitat patch. While there are likely many alternative methods for evaluating conservation quality of pine rockland habitat, peer reviewers of the proposed rule agreed that our methodology is sound and that the resulting determination for unoccupied critical habitat is appropriate.

(9) *Comment:* One commenter suggested technical corrections to sections of the proposed rule pertaining to characteristic pine rockland vegetation, related to scientific names.

Our Response: We appreciate the comment and have incorporated these corrections into the *Physical or Biological Features,* the *Primary Constituent Elements,* and the Regulation Promulgation sections of the final rule, below.

(10) *Comment:* One commenter stated that the ''antenna field'' area of mowed pine rockland bordered on the north by Coral Reef Drive (152nd Street) and on the east by SW 117th Street would support both *Brickellia mosieri* and *Linum carteri* var. *carteri,* and that it is possible that one or both plants are there already. The commenter further stated that, although the area has been mown for decades, the vegetation is primarily native pine rockland plants that have adapted to the mowing by growing prostrate instead of vertically.

Our Response: Please see our response to Peer Review Comment (5), above, with regard to how these areas were handled in the methodology for designation. In addition, a survey of this area has recently been conducted, and neither *Brickellia mosieri* nor *Linum carteri* var. *carteri* were found. However, we continue to actively communicate with both USCG and Miami-Dade County, and are supportive of conservation measures that would benefit pine rockland plants on these lands (*e.g.,* optimizing mowing regime).

Summary of Changes From Proposed Rule

Based on information we received in comments regarding *Brickellia mosieri* and *Linum carteri* var. *carteri,* we refined our description of physical or biological features and primary constituent elements for both plants to include corrections to the following scientific names, in order to more accurately describe the characteristic vegetation of pine rocklands on the Miami Rock Ridge:

(1) *Lysiloma bahamense* has been changed to *L. latisiliquum;*

(2) *Thrinax morrisii* has been deleted;

(3) *Rapanea punctata* has been changed to *Myrsine floridana;*

(4) *Dodonaea viscosa* has been deleted;

(5) *Quercus elliottii* has been changed to *Q. pumila;*

(6) *Chamaecrista fasciculata* has been changed to *C. deeringiana; and*

(7) *Zamia pumila* has been changed to *Z. integrifolia.*

These revisions have also been made in the critical habitat discussion as well as in the Regulation Promulgation section of this final rule.

We also made revisions and refinements of the proposed critical habitat designation, and described these amendments in our document making available the draft economic analysis and reopening the proposed rule's comment period (79 FR 41211; July 15, 2014). Please refer to that notice for details; those revisions, with the exception of the proposed additions on Department of Defense lands, are reflected in this final rule, and described below in *Criteria Used To Identify Critical Habitat.*

Since publishing the revised proposed critical habitat designation on July 15, 2014 (79 FR 41211), we have determined that three unoccupied areas on Department of Defense lands (Homestead Air Reserve Base and the Special Operations Command South Headquarters) meet the criteria for exemption from critical habitat designation under section 4(a)(3) of the Act (discussed under the Exemptions section, below), and we have removed these from this final designation. The exemptions result in the removal of one area (one subunit; approximately 5.2 ha (12.9 ac)) from the critical habitat designation for *Brickellia mosieri,* and three areas (two subunits; totaling approximately 7.0 ha (17.3 ac)) from the critical habitat designation for *Linum carteri* var. *carteri.* The amount of critical habitat designated for each plant in this final rule (1,062 ha (2,624 ac) for *B. mosieri* and 1,072 ha (2,649 ac) for *L. c.* var. *carteri*) reflects these exempted areas.

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features within an area, we focus on the principal biological or physical constituent elements (primary constituent elements such as roost sites, nesting grounds, seasonal wetlands, water quality, tide, soil type) that are essential to the conservation of the species. Primary constituent elements are those specific elements of the physical or biological features that provide for a species' life-history processes and are essential to the conservation of the species.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. We designate critical habitat in areas outside the geographical area occupied by a species only when a designation limited to its range would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific and commercial data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, other unpublished materials, or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to insure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) section 9 of the Act's prohibitions on taking any individual of the species, including taking caused by actions that affect habitat. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Physical or Biological Features

In accordance with section 3(5)(A)(i) and 4(b)(1)(A) of the Act and regulations at 50 CFR 424.12, in determining which areas within the geographical area occupied by the species at the time of listing to designate as critical habitat, we consider the physical or biological features (PBFs) essential to the conservation of the species and which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical, geographical, and ecological distributions of a species.

We derive the specific PBFs essential for *Brickellia mosieri* and *Linum carteri* var. *carteri* from studies of the plants' habitat, ecology, and life history as described in the Critical Habitat section of the proposed rule to designate critical habitat published in the **Federal Register** on October 3, 2013 (78 FR 61293), and in the information presented below. Additional information can be found in the final listing rule published in the **Federal Register** on September 4, 2014 (79 FR 52567). The PBFs for *Brickellia mosieri* and *Linum carteri* var. *carteri* were defined on the basis of the habitat features of the areas occupied by the plants at the time of listing, which included substrate types, plant community structure, and associated plant species. The PBFs below include an updated description of the PBF related to ''Cover or Shelter.'' We have determined that *B. mosieri* and *L. c.* var. *carteri* require the following PBFs:

Space for Individual and Population Growth

Brickellia mosieri and *Linum carteri* var. *carteri* are endemic to, and occur exclusively within, pine rockland habitat on the Miami Rock Ridge outside of Everglades National Park (ENP) in Miami-Dade County in south Florida. This community and associated native plant species are described in the Status Assessment for *Brickellia mosieri* and *Linum carteri* var. *carteri* section in the proposed listing rule published in the **Federal Register** on October 3, 2013 (78 FR 61273). Pine rocklands are a fire-maintained ecosystem characterized by an open canopy and understory and by a limestone substrate (often exposed). Open canopy conditions are required to allow sufficient sunlight to reach the herbaceous layer and permit growth and flowering of *B. mosieri* and *L. c.* var. *carteri.* These plants also require a limestone substrate to provide suitable growing conditions (*e.g.,* pH, nutrients, anchoring, and proper drainage). This combination of ecosystem characteristics (*i.e.,* open canopy and limestone substrate) occurs only in pine rockland habitats (as opposed to rockland hammock, which occurs in conjunction with pine rockland and has a limestone substrate but a closed canopy). Therefore, based on this information, we identify pine rockland habitats to be a PBF for these plants.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

Soils—Substrates supporting *Brickellia mosieri* and *Linum carteri* var. *carteri* for anchoring or nutrient absorption are composed of oolitic limestone that is at or very near the surface. Solution holes occasionally form where the surface limestone is dissolved by organic acids. There is typically very little soil development, consisting primarily of accumulations of low-nutrient sand, marl, clayey loam, and organic debris found in solution holes, depressions, and crevices on the limestone surface (FNAI 2010, p. 62). However, extensive sandy pockets can be found at the northern end of the Miami Rock Ridge, beginning from approximately North Miami Beach and extending south to approximately SW. 216 Street (which runs east-west approximately one-half mile south of Quail Roost Pineland) (Service 1999, p. 3–162). In this area (the northern Biscayne region), pine rockland soils are primarily quartz sands classified as Opalocka sand-rock outcrop complex. This region has the least exposed rock. In the southern Biscayne, or Redlands, region to the south, pine rockland soils are rockier (*i.e.,* exposed rock is the predominant surface) and are primarily classified as Cardsound silty clay loam-rock outcrop complex. Other soil types that are loosely associated with pine rocklands include Udorthents (in the northern half of the plants' current ranges) and Krome very gravelly loam (in the southern half). Therefore, based on the information above, we identify substrate derived from oolitic limestone to provide anchoring and nutritional requirements to be a PBF for these plants.

Cover or Shelter

Pine rockland is characterized by an open canopy of *Pinus elliottii* var. *densa* (South Florida slash pine). Subcanopy development is rare in well-maintained pine rocklands, with only occasional hardwoods such as *Lysiloma latisiliquum* (wild tamarind) and *Quercus virginiana* (live oak) growing to tree size in Miami Rock Ridge pinelands (Snyder *et al.* 1990, p. 253). The shrub/understory layer is also characteristically open, although the height and density of the shrub layer varies based on fire frequency, with understory plants growing taller and more dense as time since fire increases. Subcanopy/shrub species that typically occur include, but may not be limited to, *Serenoa repens* (saw palmetto), *Sabal palmetto* (cabbage palm), *Coccothrinax argentata* (silver palm), *Myrica cerifera* (wax myrtle), *Myrsine floridana* (myrsine), *Metopium toxiferum* (poisonwood), *Byrsonima lucida* (locustberry), *Tetrazygia bicolor* (tetrazygia), *Guettarda scabra* (rough velvetseed), *Ardisia escallonioides* (marlberry), *Psidium longipes* (mangroveberry), *Sideroxylon salicifolium* (willow bustic), and *Rhus copallinum* (winged sumac) (FNAI 2010, pp. 61–62). Short-statured shrubs may include, but are not limited to, *Quercus pumila* (running oak), *Randia aculeata* (white indigoberry), *Crossopetalum ilicifolium* (Christmas berry), *Morinda royoc* (redgal), and *Chiococca alba* (snowberry) (FNAI 2010, p. 62). Understory vegetation may include, but is not limited to: *Andropogon* spp.; *Schizachyrium gracile, S. rhizomatum,* and *S. sanguineum* (bluestems); *Aristida purpurascens* (arrowfeather threeawn); *Sorghastrum secundum* (lopsided Indiangrass); *Muhlenbergia capillaris* (hairawn muhly); *Rhynchospora floridensis* (Florida white-top sedge); *Tragia saxicola* (pineland noseburn); *Echites umbellata* (devil's potato); *Croton linearis* (pineland croton); *Chamaesyce* spp. (sandmats); *Chamaecrista deeringiana* (partridge pea); *Zamia integrifolia* (coontie); and *Anemia adiantifolia* (maidenhair pineland fern) (FNAI 2010, p. 62). An open canopy and understory are required to allow sufficient sunlight to reach the herbaceous layer and permit growth and flowering of *B. mosieri* and *L. c.* var. *carteri.* Therefore, based on the information above, we identify vegetation composition and structure that allows for adequate sunlight, and space for individual growth and population expansion, to be a PBF for these plants.

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Brickellia mosieri—The reproductive biology and needs of *B. mosieri* have not been studied (Bradley and Gann 1999, p. 12), and our knowledge of the ecology of the species related to reproduction needs primarily consists of observed habitat requirements and demographic trends. Field observations indicate that the species does not usually occur in great abundance; populations are typically sparse and contain a low density of plants, even in well-maintained pine rockland habitat (Bradley and Gann 1999, p. 12). Bradley (2013b, pers. comm.) estimated that, based on this observation, the minimum habitat patch size to support a sustaining population may be approximately 2 ha (5 ac), although no

studies have been conducted to evaluate this estimate. Some occupied sites are less than 2 ha (5 ac) in size, but it is not known whether these populations are sustainable in the long term.

Reproduction is sexual (Bradley and Gann 1999, p. 12), but specific pollinators or dispersers are unknown. Flower morphology suggests the species may be pollinated by butterflies, bees, or both (Koptur 2013, pers. comm.). Wind is one likely dispersal vector (Gann 2013b, pers. comm.), as is seed dispersal by animals. Within pine rocklands, more than 50 species of butterflies have been observed that may act as pollinators for *Brickellia mosieri* . Similarly, a large variety of native and nonnative bee species are known to pollinate pine rockland plants, which may include *B. mosieri.* Declines in pollinator visitation may cause decreased seed set or fruit production, which could lead to lower seedling establishment and numbers of mature plants. The availability of pollinators of appropriate type and sufficient numbers is necessary for *B. mosieri* to reproduce and ensure sustainable populations. Because the specific type(s) and number of pollinators of *B. mosieri* are unknown, and may include non-generalist species closely tied to pine rockland habitats, preserving and restoring connectivity of pine rockland habitat fragments is essential to the long-term conservation of the species. Sufficient connectivity of pine rockland habitat is also necessary to support establishment of new populations through seed dispersal, and to preserve and enhance genetic diversity.

Therefore, based on the information above, we identify habitat connectivity of sufficient size and suitability, or habitat that can be restored to these conditions that supports the species' growth, distribution, and population expansion, to be a PBF for *Brickellia mosieri.*

Linum carteri var. *carteri*—The reproductive needs of *L. c.* var. *carteri* are not well understood. Maschinski (2006, p. 83) reported that *L. c.* var. *carteri* has typical behavior for an early successional plant—plants grow to reproductive status quickly, and populations typically contain a higher density of plants. The minimum habitat patch size to support a sustaining population may be smaller than that needed for *Brickellia mosieri,* possibly as small as 0.4 ha (1 ac) (Bradley 2013b, pers. comm.), although no studies have been conducted to evaluate this estimate. Reproduction is believed to be sexual (Bradley and Gann 1999, p. 71), but specific pollinators are unknown. Flower morphology suggests this variety may also be pollinated by butterflies or bees, or both (Koptur 2013, pers. comm.). Alternatively, Mosquin and Hayley (1967, p. 1278) suggested *L. c.* var. *carteri* may be self-pollinated. Dispersal agents are unknown, but most likely include animal and human-related vectors in the existing landscape.

Therefore, given the uncertainty regarding specific pollinators and dispersal vectors, the importance of connectivity of pine rockland habitat discussed above for *Brickellia mosieri* also applies to *Linum carteri* var. *carteri.* We identify habitat connectivity of sufficient size and suitability, or habitat that can be restored to these conditions to support the species' growth, distribution, and population expansion, to also be a PBF for *L. c.* var. *carteri.*

Habitats Protected From Disturbance or Representative of the Historical, Geographic, and Ecological Distributions of *Brickellia mosieri* and *Linum carteri* var. *carteri*

Brickellia mosieri and *Linum carteri* var. *carteri* continue to occur in habitats that are protected from incompatible human-generated disturbances and are only partially representative of the plants' historical, geographical, and ecological distributions because their ranges within these habitats has been reduced. These plants are still found in their representative plant communities of pine rocklands. Representative communities are located on Federal, State, local, and private lands that implement habitat management activities which benefit these plants.

Disturbance Regime—Pine rockland is dependent on some degree of disturbance, most importantly from natural or prescribed fires (Loope and Dunevitz 1981, p. 5; Snyder *et al.* 2005, p. 1; Bradley and Saha 2009, p. 4; Saha *et al.* 2011, pp. 169–184; FNAI 2010, p. 63). These fires are a vital component in maintaining native vegetation, such as *Brickellia mosieri* and *Linum carteri* var. *carteri,* which require high light conditions and exposed substrate. Without fire, succession from pine rockland to rockland hammock (an upland tropical hardwood forest occurring over limestone) is rapid, and understory species such as *B. mosieri* and *L. c.* var. *carteri* are shaded out by dense canopy and deep leaf litter. In addition, displacement of native species by invasive, nonnative plants often occurs.

Hurricanes and other significant weather events also create openings in the pine rockland canopy (FNAI 2010, p. 63), although these types of disturbances are more sporadic in nature and may pose a threat to small, isolated populations such as those that remain of *Brickellia mosieri* and *Linum carteri* var. *carteri.* For *L. c.* var. *carteri,* mowing may also serve as another means of maintaining an open canopy where the plant occurs in firebreaks, rights-of-way, and cleared fields. However, in order to avoid potential negative impacts, the timing of mowing is critical and should be conducted after flowering has occurred (see *Demographics, Reproductive Biology and Population Genetics of L. c.* var. *carteri* in the proposed listing rule published October 3, 2013 (78 FR 61273)). Mechanical control of hardwoods may also help maintain an open canopy in pine rockland, but cannot entirely replace fire since it does not have the same benefits related to removal of leaf litter and nutrient cycling. Natural and prescribed fire remains the primary and ecologically preferred disturbance regime for pine rockland.

Brickellia mosieri tends to occur on exposed limestone with minimal organic litter and in areas with only minor amounts of substrate disturbance (Bradley and Gann 1999, p. 11). In contrast, *Linum carteri* var. *carteri* is currently associated with pine rocklands that have undergone some sort of substrate disturbance (*e.g.,* firebreaks, canal banks, edges of railway beds). All known occurrences over the last 15 years have been within either scarified pine rockland, disturbed areas adjacent to or within pine rocklands, or completely disturbed areas having a limestone substrate (Bradley and Gann 1999, p. 71; Bradley 2013a, pers. comm.). Inadequate fire management, resulting in closed canopy conditions, may have excluded *L. c.* var. *carteri* (which responds positively to low competition and high light environments) from otherwise suitable pine rocklands habitat (Bradley and Gann 1999, p. 71). Alternatively, this variety may only proliferate on sites where exposed substrate occurs following disturbance; historically this may have occurred following hurricanes (*e.g.,* under tip-up mounds of fallen trees), animal disturbance, or fire (Gann 2013a, pers. comm.). Whether current occurrences of *L. c.* var. *carteri* reflect a need for higher light conditions than *B. mosieri,* a requirement for disturbed substrate, or some combination of these, or other unidentified factors, is unknown, and microhabitat data for either plant are generally lacking. The best available scientific data suggest that both plants require a similar disturbance regime to maintain the open canopy and

low litter conditions characteristics of pine rockland habitat, and thereby maintain persistent populations.

Therefore, based on the information above, we identify natural or prescribed fire, or other disturbance regimes that maintain the pine rockland habitat, to be a PBF for these plants.

Primary Constituent Elements

Under the Act and its implementing regulations, we are required to identify the physical or biological features essential to the conservation of *Brickellia mosieri* and *Linum carteri* var. *carteri* in areas occupied at the time of listing, focusing on the features' primary constituent elements (PCEs). PCEs are those specific elements of the PBFs that provide for a species' life-history processes and are essential to the conservation of the species.

Based on our current knowledge of the PBFs and habitat characteristics required to sustain the plants' life-history processes, we determine that the PCEs specific to *Brickellia mosieri* and *Linum carteri* var. *carteri* are:

(1) Areas of pine rockland habitat that contain:

(a) Open canopy, semi-open subcanopy, and understory;

(b) Substrate of oolitic limestone rock; and

(c) A plant community of predominately native vegetation that may include, but is not limited to:

(i) Canopy vegetation dominated by *Pinus elliottii* var. *densa* (South Florida slash pine);

(ii) Subcanopy vegetation that may include, but is not limited to, *Serenoa repens* (saw palmetto), *Sabal palmetto* (cabbage palm), *Coccothrinax argentata* (silver palm), *Myrica cerifera* (wax myrtle), *Myrsine floridana* (myrsine), *Metopium toxiferum* (poisonwood), *Byrsonima lucida* (locustberry), *Tetrazygia bicolor* (tetrazygia), *Guettarda scabra* (rough velvetseed), *Ardisia escallonioides* (marlberry), *Psidium longipes* (mangroveberry), *Sideroxylon salicifolium* (willow bustic), and *Rhus copallinum* (winged sumac);

(iii) Short-statured shrubs that may include, but are not limited to, *Quercus pumila* (running oak), *Randia aculeata* (white indigoberry), *Crossopetalum ilicifolium* (Christmas berry), *Morinda royoc* (redgal), and *Chiococca alba* (snowberry); and

(iv) Understory vegetation that may include, but is not limited to: *Andropogon* spp.; *Schizachyrium gracile, S. rhizomatum,* and *S. sanguineum* (bluestems); *Aristida purpurascens* (arrowfeather threeawn); *Sorghastrum secundum* (lopsided Indiangrass); *Muhlenbergia capillaris* (hairawn muhly); *Rhynchospora floridensis* (Florida white-top sedge); *Tragia saxicola* (pineland noseburn); *Echites umbellata* (devil's potato); *Croton linearis* (pineland croton); *Chamaesyce* spp. (sandmats); *Chamaecrista deeringiana* (partridge pea); *Zamia integrifolia* (coontie); and *Anemia adiantifolia* (maidenhair pineland fern).

(2) A disturbance regime that naturally or artificially duplicates natural ecological processes (*e.g.,* fire, hurricanes, or other weather events) and that maintains the pine rockland habitat as described in PCE (1).

(3) Habitats that are connected and of sufficient area to sustain viable populations of *Brickellia mosieri* and *Linum carteri* var. *carteri* in the pine rockland habitat as described in PCE (1).

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features that are essential to the conservation of the species and which may require special management considerations or protection. The features essential to the conservation of *Brickellia mosieri* and *Linum carteri* var. *carteri* may require special management considerations or protection to reduce threats related to habitat loss, fragmentation, and modification primarily due to development; inadequate fire management; nonnative, invasive plants; and sea level rise. For an indepth discussion of threats, see Summary of Factors Affecting the Species in our proposed listing rule published in the **Federal Register** on October 3, 2013 (78 FR 61273), and as updated in our final listing rule published in the **Federal Register** on September 4, 2014 (79 FR 52567). For a discussion of the special management considerations or protection for the PBFs in this critical habitat designation, see the discussion in the proposed critical habitat rule published in the **Federal Register** on October 3, 2013 (78 FR 612793).

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b) we review available information pertaining to the habitat requirements of the species and identify occupied areas at the time of listing that contain the features essential to the conservation of the species. If, after identifying areas occupied by the species at the time of listing, we determine that those areas are inadequate to ensure conservation of the species, in accordance with the Act and our implementing regulations at 50 CFR 424.12(e) we then consider whether designating additional areas—outside those occupied at the time of listing—are essential for the conservation of the species.

In this rule, we are designating as critical habitat habitat both within the geographical area occupied by these plants at the time of listing, and outside the geographical area occupied by these plants at the time of listing but within their historical range, because such areas are essential for the conservation of these plants. We used habitat and historical occurrence data, and applied general conservation design principles, to identify unoccupied habitat essential for the conservation of these plants.

To determine the general extent, location, and boundaries of critical habitat, the Service used the following sources of information:

(1) Historical and current records of *Brickellia mosieri* and *Linum carteri* var. *carteri* occurrences and distributions found in publications, reports, personal communications, and associated voucher specimens housed at museums and private collections;

(2) FNAI, IRC, and FTBG GIS data showing the location and extent of documented occurrences of *Brickellia mosieri* and *Linum carteri* var. *carteri,* as well as occurrence data for other imperiled pine rockland species;

(3) Reports and databases prepared by botanists with IRC and FTBG. Some of these were funded by the Service, while others were requested or volunteered by biologists with IRC or FTBG;

(4) ESRI ArcGIS online basemap aerial imagery (collected December 2010) and Digital Orthophoto Quarter Quadrangles (DOQQs; 1-m true color; collected 2004) of Miami-Dade County. Because pine rockland habitat has a recognizable signature in these aerial photographs, the presence of PCEs was partially determined through evaluation of this imagery; and

(5) GIS data depicting soils (Soil Service Geographic (SSURGO) dataset), land cover (South Florida Water Management District Land Use and Cover 2008–2009), and elevation (Dade County LiDAR 88—2003) within Miami-Dade County; these data were also used to determine the presence of PCEs.

Due to the lack of existing taxa-specific data or recommendations related to conservation design (*e.g.,*

minimum area or number of populations needed for recovery), we used general conservation design principles in conjunction with the best available data for *Brickellia mosieri* and *Linum carteri* var. *carteri* to identify those unoccupied pine rocklands with the highest conservation quality—that is, those areas that currently provide the best quality habitat and are likely to continue to do so in the future, or areas that have the highest restoration potential. Guidelines for conservation design, which have been developed using island biogeography models, are highly relevant to areas such as the fragmented pine rocklands of the Miami Rock Ridge (*i.e.,* pine rockland islands in a sea of urban and agriculture development). Due to the degree of habitat loss that has already occurred, application of all such guidelines are somewhat limited by the nature of the remaining habitat (*e.g.,* sizes, shapes, and locations of individual habitat patches). As such, we evaluated conservation quality of unoccupied pine rockland habitat using the following three major principles:

(1) Geographic spread—Species that are well distributed across their native ranges are less susceptible to extinction than are species confined to small portions of their ranges.

(2) Size—Large habitat patches are superior to small habitat patches, in that larger areas will support larger populations and will be less negatively impacted by edge effects. All else being equal, conservation design options that include greater areal extent are superior. When comparative circumstances are not otherwise equal, factors such as habitat quality, the presence of specific landscape features, and the spatial arrangement of habitat may offset a solely area-driven selection process.

(3) Connectivity—Habitat that occurs in less fragmented, contiguous patches is preferable to habitat that is fragmented or isolated by urban lands. Habitat patches close to one another serve species of concern better than patches situated far apart. Interconnected patches are better than isolated patches. Conservation design alternatives should seek, in order of priority:

(a) Continuity within habitat (minimize additional fragmentation);

(b) Connectedness (increase existing habitat patches); and

(c) Proximity (minimize distance between habitat patches).

Using these guiding principles, we evaluated the remaining unoccupied pine rockland habitat on the Miami Rock Ridge outside of ENP with the intent of identifying the largest patches and highest quality habitat available (patches of sufficient size and quality to support populations), in sufficient amount (*i.e.,* sufficient numbers of populations) and spatial arrangement (to provide opportunities for future migration and colonization) to provide for the conservation of *Brickellia mosieri* and *Linum carteri* var. *carteri.* Our evaluation consisted of the following steps:

(1) Using primarily aerial imagery and GIS-based vegetation and soils data, wedelineated pine rockland habitat in Miami Dade County outside of ENP. Pine rocklands were identified based on the presence of specific soil types (see ''Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements,''above), and presence of pine rockland vegetation. Fire-suppressed areas and areas where intergrading with rockland hammock occurs were also evaluated. Some former pine rockland habitat was considered too severely fire suppressed (*i.e.,* having extremely dense canopy cover) such that it is now unsuitable habitat for *Brickellia mosieri* and *Linum carteri* var. *carteri,* and unlikely to be able to be restored; these areas were not delineated as pine rocklands in our critical habitat analysis. Some cleared areas occurring over pine rockland soils were delineated, with the intent that such areas provide opportunities for restoration. The resulting habitat layer consisted of 245 habitat patches.

(2) To maximize geographic spread within the plants' historical ranges, we divided the extent of delineated habitat into five geographic areas (northeast to southwest).

(3) For each plant, we included occupied patches in final critical habitat (25 habitat patches for *Brickellia mosieri,* and 6 patches for *Linum carteri* var. *carteri*). One occurrence of *L. c.* var. *carteri* (a single plant found on a canal bank) is not included in final critical habitat due to the anomalous nature of the occurrence, and because we were not able to define patch boundaries based on any of the criteria described in (1), above. In addition, a new occurrence of *L. c.* var. *carteri* (11 plants in a firebreak) was discovered on October 17, 2014 on the Deering Estate, but outside the proposed critical habitat subunit. Because we believe that the proposed critical habitat designation contains sufficient habitat for the conservation of this plant, subunit boundaries were not revised and this occurrence is not included in the final critical habitat designation.

(4) For each plant, for the remaining (unoccupied) habitat, we excluded patches below the estimated minimum size for each plant based on expert opinion—2 ha (5 ac) for *Brickellia mosieri,* and 0.4 ha (1 ac) for *Linum carteri* var. *carteri* (see ''Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring,'' above). The resulting layers consisted of 106 habitat patches for *B. mosieri,* and 218 patches for *L. c.* var. *carteri.*

(5) For each plant, for the remaining habitat (unoccupied; 2 ha (5 ac) or greater than or equal to 0.4 ha (1 ac), *Brickellia mosieri* or *Linum carteri* var. *carteri,* respectively), we assigned a score for eight evaluation criteria designed to assess overall conservation quality of the patch, using the following five major objectives (discussed more indepth below and at *http://www.regulations.gov*):

(a) Onsite habitat quality (intact, open pine rocklands scored higher than cleared patches or patches having a closed canopy);

(b) Patch size (larger patches scored higher);

(c) Surrounding landscape composition (pine rocklands surrounded by less development scored higher);

(d) Connectivity (within each geographic area, pine rockland patches in closer proximity to each other and with greater numbers of neighbors scored higher); and

(e) Vulnerability to sea level rise (pine rockland patches located at higher elevations scored higher).

(6) For each plant, within each geographic area, we used a consequence matrix to evaluate the performance of each unoccupied pine rockland patch across the objectives described above in (5). The resulting total score of each patch was a 0.0–1.0 value, summed across all criteria, where a score of 1.0 indicates the patch in each geographic area that has the highest conservation quality, based on the defined objectives.

Using the results of the consequence matrix for each plant, we evaluated potential ''cut-off'' values for patch total score by visually assessing and comparing habitat amounts and spatial arrangements between various cut-off values in order to identify the best conservation arrangement. Because taxa-specific data and recommendations were not available regarding how much area is needed for the conservation and recovery of *Brickellia mosieri* and *Linum carteri* var. *carteri,* we applied the general conservation design principles related to connectivity, above, and principles of population viability and metapopulation theory. Small populations and plant species with limited distributions, like those of *B. mosieri* and *L. c.* var. *carteri,* are

vulnerable to relatively minor environmental disturbances (Frankham 2005, pp. 135–136), and are subject to the loss of genetic diversity from genetic drift, the random loss of genes, and inbreeding (Ellstrand and Elam 1993, pp. 217–237; Leimu *et al.* 2006, pp. 942–952). These factors increase the probability of both local extinctions and population extinction (Barrett and Kohn 1991, pp. 4, 28; Newman and Pilson 1997, p. 360; Palstra and Ruzzante 2008, pp. 3428–3447). To ameliorate these effects, the recovery of many rare plant species includes the creation of new sites or reintroductions to increase population size (each occurrence, and overall) and support genetic diversity. Sufficient area is also required to allow *B. mosieri* and *L. c.* var. *carteri* to expand their current distributions (curtailed compared to historical ranges), use habitat depending on the availability of suitable conditions (dynamic, related to time since disturbance within each patch), and maintain their ability to withstand local- or unit-level environmental fluctuations or catastrophes.

Based on our assessment, as described above, we determined that unoccupied pine rockland patches with a total score for conservation quality greater than 0.50 should be proposed for critical habitat designation. In addition, in the proposed critical habitat rule published in the **Federal Register** on October 3, 2013 (78 FR 61293), we proposed 15 supplemental pine rockland patches for critical habitat designation for one or more of the following reasons: (1) A population of *Brickellia mosieri* was previously observed in the patch (although not recently enough to consider the population extant at this time); (2) addition of the patch increases conservation quality of adjacent critical habitat; (3) addition of the patch increases connectivity of pine rockland habitat across the landscape; and (4) the patch is located at the northernmost end of these plants' historical ranges (an area not captured using the consequence matrix approach). The last category consists of four patches with conservation quality less than or equal to 0.50, due to some combination of lower onsite habitat quality, smaller size, and more development in the surrounding landscape, all of which are related to their position closer to Miami. While these patches may not represent the best habitat currently available, they do provide needed opportunities to increase these plants' geographic spread and restore the plants to the northernmost intact habitat within their historical ranges, which is more heavily impacted, and are essential to the conservation of these plants, as discussed above.

Revisions to the resulting set of habitat patches were proposed in the revised proposed rule and availability of the draft economic analysis published in the **Federal Register** on July 15, 2014 (79 FR 41211), based on new information concerning the current habitat condition of proposed areas as well as information regarding additional areas of suitable habitat that were not included in the proposed designation but that meet the definition of critical habitat. The proposed changes consisted of the removal of two unoccupied patches from the proposed designation, the revision of patch boundaries for three unoccupied areas, and the proposed designation of six new unoccupied pine rockland patches (multiple patches may make up a single subunit). For more information regarding these proposed changes, refer to that notice. We have since determined that three of the six new proposed patches (*i.e.,* three unoccupied areas on Department of Defense lands) meet the criteria for exemption from critical habitat designation under section 4(a)(3) of the Act (discussed under the Exemptions section, below), and we have removed these from the designation of critical habitat in this final rule.

Habitat Within the Geographic Range at the Time of Listing

We are designating seven critical habitat units for each plant. Five of the seven units were occupied by *Brickellia mosieri* at the time of listing; the remaining two units are within the plant's historical range, but were unoccupied at the time of listing. Three of the seven units were occupied by *Linum carteri* var. *carteri* at the time of listing; the remaining four units are within the plant's historical range, but were unoccupied at the time of listing. The occupied units include the mapped extent of each plant's population and contain the PCEs.

Within each of these occupied units is also unoccupied habitat, which is included based on our determination that such areas are essential to the conservation of these plants, as discussed above. In addition to providing sufficient habitat (area, number of patches, connectivity), this unoccupied habitat allows for the dynamic nature of pine rockland habitat. Conditions within pine rockland patches, such as the openness of the canopy and understory and the accumulation of leaf litter over the limestone substrate, vary greatly across the landscape and across time. Only a portion of the delineated habitat is suitable for *Brickellia mosieri* or *Linum carteri* var. *carteri,* or both plants, at any given time, and the size and location of suitable areas within the population is dynamic over time, being largely driven by the frequency and scale of natural or prescribed fires and other types of disturbance (*e.g.,* for *L. c.* var. *carteri,* mowing or other events that disturb the limestone substrate). Although prescribed burns are administered on conservation lands that retain *B. mosieri* or *L. c.* var. *carteri,* or both, populations, fire return intervals and scope are inconsistent. Thus, areas of pine rockland habitat that now support one or both of these plants may not support the plants in the future, as inadequate fire management removes or fragments suitable habitat. Conversely, suitable habitat conditions may return or increase in areas following natural or prescribed fires, allowing opportunities for the plants to expand or colonize these areas in the future.

The delineation of units (occupied plus unoccupied patches) also includes space to plan for the persistence of *Brickellia mosieri* and *Linum carteri* var. *carteri* populations in the face of imminent effects on habitats as a result of sea level rise. Although occupied habitat within each unit contains the PCEs, some of these areas may be altered, as a result of vegetation shifts or salt water intrusion, to an extent which cannot be predicted at this time.

In identifying unoccupied patches with these units, we considered the following additional criteria, which we incorporated into the consequence matrix described above:

(1) *Objective 1 (onsite habitat quality):* Pine rockland areas of sufficient habitat quality to support the growth and reproduction of *Brickellia mosieri* and *Linum carteri* var. *carteri.* In general, areas of intact pine rockland having an open canopy and understory are more likely to support populations of these plants over the long term. In some cases, disturbed or cleared pine rockland areas have also been included in the designation; these areas possess other desirable characteristics (*e.g.,* size, connectivity) and could allow *B. mosieri* or *L. c.* var. *carteri* to expand from areas already occupied by these plants. These areas are typically habitats within or adjacent to pine rocklands that have been affected by natural or anthropogenic impacts, but that retain areas that are still suitable for the plants. These areas would help to off-set the anticipated loss and degradation of habitat occurring or expected from the

effects of climate change (such as sea level rise) or due to development.

(2) *Objective 2 (patch size):* Pine rockland areas of sufficient size to support ecosystem processes for populations of *Brickellia mosieri* or *Linum carteri* var. *carteri.* Given areas of equal habitat quality, larger areas would be ranked higher in our evaluation.

(3) *Objective 3 (surrounding landscape composition):* Pine rockland areas within a suitable landscape to allow for natural disturbance regimes—specifically, prescribed fire—and to minimize negative impacts related to changes in hydrology or nutrient/pollution inputs from the surrounding area. Pine rocklands surrounded by other natural communities will likely provide higher quality habitat in the long term than pine rocklands that are imbedded in a highly urbanized or agricultural matrix. Given areas of equal habitat quality and size, areas with more natural communities and less urban development in the surrounding area would be ranked higher in our evaluation.

(4) *Objective 4 (connectivity):* Pine rockland areas of sufficient amount and arrangement to maintain connectivity of habitat to allow for population sustainability and expansion. Sufficient connectivity of pine rockland habitat will contribute to the availability of pollinators of appropriate type and sufficient numbers to allow *Brickellia mosieri* and *Linum carteri* var. *carteri* to reproduce and ensure sustainable populations, and to allow for population expansion through seed dispersal. Given areas of equal habitat quality, size, and surrounding landscape composition, those patches having more and closer neighbors (*i.e.,* other pine rockland patches) would be ranked higher in our evaluation.

(5) *Objective 5 (vulnerability to sea level rise):* Pine rockland areas of suitable elevation to reduce vulnerability to sea level rise. Those pine rocklands situated at higher elevations are less likely to be negatively affected by either inundation or vegetation shifts caused by changes in the salinity of the water table and soils associated with sea level rise. Given areas of equal conservation quality, as described above, those patches having a higher average elevation would be ranked higher in our evaluation.

A complete description regarding how these objectives were weighted and evaluated in our consequence matrix can be found in the supplemental materials provided with the proposed rule at *http://www.regulations.gov.*

Habitat Outside of the Geographic Range at the Time of Listing

We are designating two critical habitat units that were unoccupied by *Brickellia mosieri* at the time of listing, and four critical habitat units that were unoccupied by *Linum carteri* var. *carteri* at the time of listing, which have been determined to be essential to the conservation of these plants. These units represent portions of these plants' historical ranges in which the plants have been extirpated (see *Current Range, Population Estimates, and Status* for both plants in our proposed listing rule published in the **Federal Register** on October 3, 2013 (78 FR 61273)). In one unit, located in the northern portion of these plants' historical ranges but unoccupied by either *B. mosieri* or *L. c.* var. *carteri,* the unoccupied critical habitat patches are the only pine rockland habitat that remains in this area. While the full extent of *B. mosieri*'s historical range is unknown, due to limited data, comparing its current distribution to historical observations suggests that its range has contracted at least 30 percent (based on our revised estimate of the species' historical range as described in the final listing rule published in the **Federal Register** on September 4, 2014 (79 FR 52567)). Likewise, the historical range of *L. c.* var. *carteri* has been reduced approximately 30 percent. The reductions in the historical ranges of these plants have occurred almost entirely in their northern portions, between Pinecrest and South Miami/Coconut Grove. As noted earlier, little pine rockland habitat has escaped urban development in this area, and those patches that remain are of lesser conservation quality due to lower onsite habitat quality, smaller patch sizes, and higher amounts of development in the surrounding landscape. While these patches may not represent the best pine rockland habitat currently available, they provide needed habitat to increase these plants' geographic spread to currently unoccupied portions of their historical ranges, and are essential for the conservation of the two plants.

In summary, for occupied habitat within the geographic area occupied by *Brickellia mosieri* or *Linum carteri* var. *carteri* at the time of listing, we delineated critical habitat unit boundaries by evaluating habitat suitability of pine rockland habitat within this geographic area, and retained those areas that contain some or all of the PCEs to support life-history functions essential for conservation of these plants.

For unoccupied habitat within the geographic area occupied by *Brickellia mosieri* or *Linum carteri* var. *carteri* at the time of listing, we delineated critical habitat unit boundaries by evaluating the five objectives incorporated into the consequence matrix (see discussion above).

For habitat outside the geographic area occupied by the species at the time of listing, we delineated critical habitat unit boundaries based on the availability of remaining pine rockland habitat in the unit. All four available patches were included in the delineation in order to provide sufficient area for *Brickellia mosieri* and *Linum carteri* var. *carteri* to expand their current restricted ranges.

When determining critical habitat boundaries within this final rule, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features for *Brickellia mosieri* and *Linum carteri* var. *carteri.* The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this final rule have been excluded by text in the rule and are not designated as critical habitat. Therefore, a Federal action involving these lands will not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document in the Regulation Promulgation section. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0108, and at the field office responsible for the designation (see **FOR FURTHER INFORMATION CONTACT**, above).

Units and subunits are designated based on sufficient elements of physical or biological features being present to support the life processes of *Brickellia mosieri* and *Linum carteri* var. *carteri.* Some subunits contain all of the identified elements of physical or biological features and support multiple

life processes. Some subunits contain only some elements of the physical or biological features necessary to support particular use of that habitat by *B. mosieri* or *L. c.* var. *carteri.*

Final Critical Habitat Designation

We are designating seven units, each, as critical habitat for *Brikellia mosieri* and *Linum carteri.* var. *carteri.* The critical habitat areas described below constitute our best assessment at this time of areas that meet the definition of critical habitat.

Brickellia mosieri

The seven units (all located in Miami-Dade County, Florida) we are designating as critical habitat for *Brickellia mosieri* are: (1) Unit BM1: Trinity Pineland and surrounding areas; (2) Unit BM2: Nixon Smiley Pineland Preserve and surrounding areas; (3) Unit BM3: U.S. Department of Agriculture (USDA) Subtropical Horticultural Research Station and surrounding areas; (4) Unit BM4: Richmond Pinelands and surrounding areas; (5) Unit BM5: Quail Roost Pineland and surrounding areas; (6) Unit BM6: Camp Owaissa Bauer and surrounding areas; and (7) Unit BM7: Navy Wells Pineland Preserve and surrounding areas. Because of the highly fragmented nature of the remaining pine rockland habitat, these large overall unit boundaries encompass multiple, smaller designations (*i.e.*, subunits) within each unit; only these subunits within the unit boundaries meet the definition of critical habitat. Subunit designations identify individual habitat patches, or multiple habitat patches having the same occupancy status that are only separated by a road. Table 1 shows occupancy, area, and land ownership for each subunit within the critical habitat designation for *B. mosieri.*

TABLE 1—OCCUPANCY (O = OCCUPIED, U = UNOCCUPIED), AREA, AND LAND OWNERSHIP OF DESIGNATED CRITICAL HABITAT SUBUNITS FOR BRICKELLIA MOSIERI. AREA ESTIMATES REFLECT ALL LAND WITHIN CRITICAL HABITAT UNIT/SUBUNIT BOUNDARIES. SUBSTANTIAL OVERLAP EXISTS WITH AREAS BEING DESIGNATED FOR LINUM CARTERI. VAR. CARTERI

Unit	Subunit	Occupancy	Hectares	Acres	Land ownership by type [1]
BM1	BM1A	U	5	13	County/Local.
	BM1B	U	12	30	State, County/Local, Private/Other.
Unit Total			*18*	*43*	
BM2	BM2A	U	32	78	State, County/Local, Private/Other.
	BM2B	U	47	115	County/Local.
	BM2C	U	8	19	State.
	BM2D	O	3	8	County/Local.
	BM2E	O	2	5	County/Local.
	BM2F	U	1	2	County/Local.
	BM2G	O	16	39	State, County/Local.
Unit Total			*108*	*267*	
BM3	BM3A	U	2	6	State.
	BM3B	U	59	146	Federal, County/Local, Private/Other.
	BM3C	U	11	28	State, County/Local, Private/Other.
	BM3D	U	3	6	County/Local.
	BM3E	U	34	84	State, County/Local.
	BM3F	U	6	15	State, County/Local.
	BM3G	U	5	11	County/Local.
	BM3H	U	8	19	County/Local, Private/Other.
Unit Total			*127*	*315*	
BM4	BM4A	U	89	219	Federal, County/Local, Private/Other.
	BM4B	O	137	339	Federal, County/Local, Private/Other.
	BM4C	U	10	24	Federal, County/Local.
	BM4D	U	17	42	County/Local.
	BM4E	O	124	306	Federal, County/Local.
	BM4F	U	5	13	County/Local, Private/Other.
	BM4G	O	6	15	Private/Other.
	BM4H	U	7	17	County/Local.
Unit Total			*395*	*975*	
BM5	BM5A	O	25	62	State, County/Local, Private/Other.
	BM5B	U	6	14	County/Local, Private/Other.
	BM5C	U	4	10	County/Local.
	BM5D	O	3	8	County/Local, Private/Other.
	BM5E	U	22	53	State, County/Local, Private/Other.
	BM5F	U	3	7	County/Local.
	BM5G	U	4	10	County/Local, Private/Other.
	BM5H	U	9	22	State, County/Local.
	BM5I	U	6	14	County/Local, Private/Other.
	BM5J	U	13	31	County/Local, Private/Other.
	BM5K	U	3	6	Private/Other.
Unit Total			*96*	*238*	
BM6	BM6A	U	38	93	State, County/Local, Private/Other.
	BM6B	U	14	35	County/Local, Private/Other.
	BM6C	U	5	12	County/Local, Private/Other.
	BM6D	U	4	10	State, County/Local, Private/Other.

TABLE 1—OCCUPANCY (O = OCCUPIED, U = UNOCCUPIED), AREA, AND LAND OWNERSHIP OF DESIGNATED CRITICAL HABITAT SUBUNITS FOR BRICKELLIA MOSIERI. AREA ESTIMATES REFLECT ALL LAND WITHIN CRITICAL HABITAT UNIT/SUBUNIT BOUNDARIES. SUBSTANTIAL OVERLAP EXISTS WITH AREAS BEING DESIGNATED FOR LINUM CARTERI. VAR. CARTERI—Continued

Unit	Subunit	Occupancy	Hectares	Acres	Land ownership by type [1]
	BM6E	O	13	32	County/Local, Private/Other.
	BM6F	O	7	17	State, County/Local, Private/Other.
	BM6G	O	1	3	County/Local, Private/Other.
	BM6H	O	1	4	County/Local, Private/Other.
	BM6I	U	6	15	State, County/Local, Private/Other.
	BM6J	U	11	28	County/Local, Private/Other.
	BM6K	U	7	16	County/Local, Private/Other.
	BM6L	O	5	12	County/Local, Private/Other.
Unit Total			*112*	*276*	
BM7	BM7A	U	11	27	County/Local, Private/Other.
	BM7B	U	10	24	County/Local, Private/Other.
	BM7C	U	8	20	State, County/Local.
	BM7D	U	7	18	State, County/Local, Private/Other.
	BM7E	U	16	39	County/Local, Private/Other.
	BM7F	O	133	330	State, County/Local, Private/Other.
	BM7G	U	11	27	County/Local, Private/Other.
	BM7H	U	11	26	State, County/Local, Private/Other.
Unit Total			*206*	*510*	
CH Total			*1,062*	*2,624*	

Note: Area sizes may not sum due to rounding.
[1] Ownership information is based on Miami-Dade County parcel data (July 2013) and FNAI's Florida Managed Lands data (March 2014).

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for *Brickellia mosieri*, below.

Unit BM1: Trinity Pineland and Surrounding Areas, Miami-Dade County, Florida

Unit BM1 consists of 18 ha (43 ac) in Miami-Dade County. Within Unit BM1, there are two subunits—BM1A (County-owned) and BM1B (combination of State, County, and privately owned lands). The unit is comprised of State lands within Trinity Pineland County Park (4 ha (10 ac)); County lands primarily within A. D. ''Doug'' Barnes Park (6 ha (14 ac)); and parcels in private ownership (8 ha (19 ac)). This unit is bordered on the north by SW 24 Street, on the south by the Snapper Creek Expressway (State Road (SR) 878), on the east by SW 67 Avenue, and on the west by SW 87 Avenue. The unit is within the historical range of *Brickellia mosieri*, although data are lacking regarding historical occupancy of the specific critical habitat patches in the unit. This unit includes the only remaining pine rockland habitat in this northern portion of the Miami Rock Ridge.

This unit was not occupied by *Brickellia mosieri* at the time of listing but is essential to the conservation of the species because it serves to protect habitat needed to recover the species, reestablish wild populations within the historical ranges of the species, and maintain populations throughout the historical distribution of the species in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *B. mosieri* be extirpated from one of its current locations.

Unit BM2: Nixon Smiley Pineland Preserve and Surrounding Areas, Miami-Dade County, Florida

Unit BM2 consists of approximately 108 ha (267 ac) of habitat in Miami-Dade County. Within Unit BM2, there are seven subunits (BM2A–BM2G) comprising primarily conservation lands and including four larger areas plus three smaller areas. The unit is comprised of State lands within Camp Matecumbe, Tamiami Pineland Complex Addition, and Rockdale Pineland (49 ha (121 ac)); County/local lands primarily within Nixon Smiley Pineland Preserve, Tamiami #8 (Nixon Smiley Addition) Pineland, Pine Shore Pineland Preserve, Ron Ehman Park, and Rockdale Pineland Addition (59 ha (146 ac)); and small portions of parcels in private or other ownership (less than 1 ha (less than 1 ac)). This unit is bordered on the north by SW 104 Street, on the south by SW 152 Street (Coral Reef Drive), on the east by U.S. 1 (South Dixie Highway), and on the west by SW 177 Avenue (Krome Avenue).

This unit is composed of both occupied and unoccupied habitat. Some habitat within the unit was occupied by *Brickellia mosieri* (three occurrences; approximately 21 ha (52 ac)) at the time of listing. This occupied habitat contains some or all of the PCEs, including pine rockland habitat, oolitic limestone substrate, suitable vegetation composition and structure, natural or artificial disturbance regimes, and habitat connectivity of sufficient size and suitability. The PCEs in this unit may require special management considerations or protection to address threats of habitat fragmentation; inadequate fire management; competition with nonnative, invasive plants; and sea level rise. In some cases, these threats are being addressed or coordinated with our partners and landowners to implement needed actions.

Some of the unoccupied habitat within this unit was historically occupied by *Brickellia mosieri*, although it was not occupied by the species at the time of listing. This unoccupied habitat is essential to the conservation of *B. mosieri* because it serves to protect habitat needed to recover the species, reestablish wild populations within the historical ranges of the species, and maintain populations throughout the historical distribution of the species in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *B. mosieri* be extirpated from one of its current locations.

Unit BM3: USDA Subtropical Horticultural Research Station and Surrounding Areas, Miami-Dade County, Florida

Unit BM3 consists of approximately 127 ha (315 ac) of habitat in Miami-Dade County. Within Unit BM3, there are eight subunits (BM3A–BM3H), including two larger areas (U.S. Department of Agriculture (USDA) Subtropical Horticultural Research Station, and Deering Estate at Cutler) plus six smaller areas surrounding these. The unit is comprised of Federal lands within the USDA Subtropical Horticultural Research Station (59 ha (145 ac)); State lands within the R. Hardy Matheson Preserve, Ludlam Pineland, Deering Estate at Cutler, and Deering Estate South Addition (45 ha (112 ac)); County/local lands within Coral Reef Park, Ned Glenn Nature Preserve, and Bill Sadowski Park (15 ha (38 ac)); and parcels in private ownership (8 ha (19 ac)). This unit is bordered on the north by SW 112 Street, on the south by the intersection of Old Cutler Road and Franjo Road (County Road (CR) 977), on the east by the Atlantic Ocean, and on the west by U.S. 1 (South Dixie Highway). The unit is within the historical range of *Brickellia mosieri*, although data are lacking regarding historical occupancy of the specific critical habitat patches in the unit.

This unit was unoccupied by *Brickellia mosieri* at the time of listing but is essential to the conservation of the species because it serves to protect habitat needed to recover the species, reestablish wild populations within the historical ranges of the species, and maintain populations throughout the historical distribution of the species in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *B. mosieri* be extirpated from one of its current locations.

Unit BM4: Richmond Pinelands and Surrounding Areas, Miami-Dade County, Florida

Unit BM4 consists of approximately 395 ha (975 ac) in Miami-Dade County. Within Unit BM4, there are eight subunits (BM4A–BM4H), most within the Richmond Pinelands complex (made up of Federal and County-owned lands, as well as land owned by the University of Miami). The unit is comprised of Federal lands owned by the USCG (Homeland Security), U.S. Army Corps of Engineers (ACOE; Department of Defense), U.S. Prison Bureau (Department of Justice), and the U.S. Department of Commerce/National Oceanic and Atmospheric Administration (NOAA) (75 ha (185 ac)); County/local lands within and adjacent to Larry and Penny Thompson Park, Martinez Pineland, Zoo Miami, and Eachus Pineland (239 ha (590 ac)); and parcels in private or other ownership (81 ha (200 ac)). This unit is bordered on the north by SW 152 Street (Coral Reef Drive), on the south by SW 200 St (Quail Drive/SR 994), on the east by U.S. 1 (South Dixie Highway), and on the west by SW 177 Avenue (Krome Avenue).

This unit is composed of both occupied and unoccupied habitat. Some habitat within the unit was occupied by *Brickellia mosieri* (approximately 267 ha (660 ac)) at the time of listing. All occupied habitat occurs within the Richmond Pinelands, which together compose the largest remaining group of contiguous fragments of pine rockland habitat outside of ENP. This occupied habitat contains all of the PCEs, including pine rockland habitat, oolitic limestone substrate, suitable vegetation composition and structure, natural or artificial disturbance regimes, and habitat connectivity of sufficient size and suitability. The PCEs in this unit may require special management considerations or protection to address threats of habitat loss and fragmentation; inadequate fire management; competition with nonnative, invasive plants; and sea level rise. In some cases, these threats are being addressed or coordinated with our partners and landowners to implement needed actions.

Some of the unoccupied habitat within this unit was historically occupied by *Brickellia mosieri*, although it was not occupied by the species at the time of listing. This unoccupied habitat is essential to the conservation of *B. mosieri* because it serves to protect habitat needed to recover the species, reestablish wild populations within the historical ranges of the species, and maintain populations throughout the historical distribution of the species in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *B. mosieri* be extirpated from one of its current locations.

Unit BM5: Quail Roost Pineland and Surrounding Areas, Miami-Dade County, Florida

Unit BM5 consists of approximately 96 ha (238 ac) in Miami-Dade County. Within Unit BM5, there are 11 subunits (BM5A–BM5K), including 4 larger areas plus 7 smaller areas surrounding these. The unit is comprised of State lands within Quail Roost Pineland, Goulds Pineland and Addition, and Silver Palm Groves Pineland (39 ha (97 ac)); County/local lands including Black Creek Forest, Rock Pit #46, and lands owned by the School Board of Miami-Dade County (15 ha (37 ac)); and parcels in private ownership (42 ha (104 ac)), including Porter-Russell Pineland owned by the Tropical Audubon Society. This unit is bordered on the north by SW 200 St (Quail Drive/SR 994), on the south by SW 248 Street, on the east by the Florida Turnpike, and on the west by SW 194 Avenue.

This unit is composed of both occupied and unoccupied habitat. Some habitat within the unit was occupied by *Brickellia mosieri* (two occurrences; approximately 28 ha (70 ac)) at the time of listing. This occupied habitat contains some or all of the PCEs, including pine rockland habitat, oolitic limestone substrate, suitable vegetation composition and structure, natural or artificial disturbance regimes, and habitat connectivity of sufficient size and suitability. The PCEs in this unit may require special management considerations or protection to address threats of habitat fragmentation; inadequate fire management; competition with nonnative, invasive plants; and sea level rise. In some cases, these threats are being addressed or coordinated with our partners and landowners to implement needed actions.

Unoccupied habitat in the unit is essential to the conservation of *Brickellia mosieri* because it serves to protect habitat needed to recover the species, reestablish wild populations within the historical ranges of the species, and maintain populations throughout the historical distribution of the species in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *B. mosieri* be extirpated from one of its current locations.

Unit BM6: Camp Owaissa Bauer and Surrounding Areas, Miami-Dade County, Florida

Unit BM6 consists of approximately 112 ha (276 ac) of habitat in Miami-Dade County. Within Unit BM6, there are 12 subunits (BM6A–BM6L), composed of 1 larger area (Camp Owaissa Bauer and its addition) and 11 smaller areas to the south. The unit is comprised of State lands within Owaissa Bauer Pineland Addition, Ingram Pineland, West Biscayne Pineland, and Fuchs Hammock Addition (20 ha (50 ac)); County/local lands including Camp Owaissa Bauer, Pine Island Lake Park, Seminole Wayside Park, and Northrop Pineland

(63 ha (156 ac)); and parcels in private ownership (28 ha (70 ac)), including the private conservation area, Pine Ridge Sanctuary. This unit is bordered on the north by SW 248 Street, on the south by SW 312 Street, on the east by SW 112 Avenue, and on the west by SW 217 Avenue.

This unit is composed of both occupied and unoccupied habitat. Some habitat within the unit was occupied by *Brickellia mosieri* (five occurrences; approximately 27 ha (67 ac)) at the time of listing. This occupied habitat contains some or all of the PCEs, including pine rockland habitat, oolitic limestone substrate, suitable vegetation composition and structure, natural or artificial disturbance regimes, and habitat connectivity of sufficient size and suitability. The PCEs in this unit may require special management considerations or protection to address threats of habitat loss and fragmentation; inadequate fire management; competition with nonnative, invasive plants; and sea level rise. In some cases, these threats are being addressed or coordinated with our partners and landowners to implement needed actions.

Some of the unoccupied habitat within this unit was historically occupied by *Brickellia mosieri.* Although it was unoccupied by the species at the time of listing, this habitat is essential to the conservation of *B. mosieri* because it serves to protect habitat needed to recover the species, reestablish wild populations within the historical ranges of the species, and maintain populations throughout the historical distribution of the species in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *B. mosieri* be extirpated from one of its current locations.

Unit BM7: Navy Wells Pineland Preserve and Surrounding Areas, Miami-Dade County, Florida

Unit BM7 consists of approximately 206 ha (510 ac) of habitat in Miami-Dade County. Within Unit BM7, there are eight subunits (BM7A–BM7H), including one larger area (Navy Wells Pineland Preserve) and seven smaller outlying areas. The unit is comprised of State lands within Palm Drive Pineland, Navy Wells Pineland #39, Navy Wells Pineland Preserve (portion), and Florida City Pineland (53 ha (132 ac)); County/local lands including primarily Sunny Palms Pineland and Navy Wells Pineland Preserve (portion) (125 ha (309 ac)); and parcels in private ownership (28 ha (68 ac)). This unit is bordered on the north by SW 320 Street, on the south by SW 368 Street, on the east by U.S. 1 (South Dixie Highway), and on the west by SW 217 Avenue.

This unit is composed of both occupied and unoccupied habitat. Some habitat in the unit was occupied by *Brickellia mosieri* (one occurrence; approximately 134 ha (330 ac)) at the time of listing. This occurrence is on Navy Wells Pineland Preserve, which is one of the largest remaining areas of pine rockland habitats outside of ENP. This occupied habitat contains all of the PCEs, including pine rockland habitat, oolitic limestone substrate, suitable vegetation composition and structure, natural or artificial disturbance regimes, and habitat connectivity of sufficient size and suitability. The PCEs in this unit may require special management considerations or protection to address threats of habitat fragmentation; inadequate fire management; competition with nonnative, invasive plants; and sea level rise. However, in Navy Wells, most of these threats are being addressed or coordinated with our partners and landowners to implement needed actions.

Some of the unoccupied habitat within this unit was historically occupied by *Brickellia mosieri.* Although it was unoccupied by the species at the time of listing, this habitat is essential to the conservation of *B. mosieri* because it serves to protect habitat needed to recover the species, reestablish wild populations within the historical ranges of the species, and maintain populations throughout the historical distribution of the species in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *B. mosieri* be extirpated from one of its current locations.

Linum carteri var. *carteri*

The seven units (all located in Miami-Dade County, Florida) we are designating as critical habitat for *Linum carteri* var. *carteri* are: (1) Unit LCC1: Trinity Pineland and surrounding areas; (2) Unit LCC2: Nixon Smiley Pineland Preserve and surrounding areas; (3) Unit LCC3: USDA Subtropical Horticultural Research Station and surrounding areas; (4) Unit LCC4: Richmond Pinelands and surrounding areas; (5) Unit LCC5: Quail Roost Pineland and surrounding areas; (6) Unit LCC6: Camp Owaissa Bauer and surrounding areas; and (7) Unit LCC7: Navy Wells Pineland Preserve and surrounding areas. Because of the highly fragmented nature of the remaining pine rockland habitat, these large overall unit boundaries encompass multiple, small designations (*i.e.*, subunits) within each unit; only these subunits within the unit boundaries are designated as critical habitat. Subunit designations identify individual habitat patches, or multiple habitat patches having the same occupancy status that are only separated by a road. Table 2 shows occupancy, area, and land ownership for each subunit within the critical habitat designation for *L. c.* var. *carteri.*

TABLE 2—OCCUPANCY (O = OCCUPIED, U = UNOCCUPIED), AREA, AND LAND OWNERSHIP OF DESIGNATED CRITICAL HABITAT SUBUNITS FOR LINUM CARTERI VAR. CARTERI. AREA ESTIMATES REFLECT ALL LAND WITHIN CRITICAL HABITAT UNIT/SUBUNIT BOUNDARIES. SUBSTANTIAL OVERLAP EXISTS WITH AREAS BEING DESIGNATED FOR BRICKELLIA MOSIERI

Unit	Subunit	Occupancy	Hectares	Acres	Land ownership by type [1]
LCC1	LCC1A	U	5	13	County/Local.
	LCC1B	U	2	4	County/Local.
	LCC1C	U	12	30	State, County/Local, Private/Other.
Unit Total			*19*	*48*	
LCC2	LCC2A	U	32	78	State, County/Local, Private/Other.
	LCC2B	U	47	115	County/Local.
	LCC2C	U	12	30	State, County/Local.
	LCC2D	U	3	8	County/Local.
	LCC2E	U	3	7	County/Local.
	LCC2F	O	16	39	State, County/Local.
Unit Total			*113*	*278*	
LCC3	LCC3A	O	2	6	State.
	LCC3B	O	1	2	County/Local, Private/Other.

TABLE 2—OCCUPANCY (O = OCCUPIED, U = UNOCCUPIED), AREA, AND LAND OWNERSHIP OF DESIGNATED CRITICAL HABITAT SUBUNITS FOR LINUM CARTERI VAR. CARTERI. AREA ESTIMATES REFLECT ALL LAND WITHIN CRITICAL HABITAT UNIT/SUBUNIT BOUNDARIES. SUBSTANTIAL OVERLAP EXISTS WITH AREAS BEING DESIGNATED FOR BRICKELLIA MOSIERI—Continued

Unit	Subunit	Occupancy	Hectares	Acres	Land ownership by type [1]
	LCC3C	O	59	146	Federal, County/Local, Private/Other.
	LCC3D	U	11	28	State, County/Local, Private/Other.
	LCC3E	U	3	6	County/Local.
	LCC3F	U	34	84	State, County/Local.
	LCC3G	U	6	15	State, County/Local.
	LCC3H	U	5	11	County/Local.
	LCC3I	U	8	19	County/Local, Private/Other.
Unit Total			*128*	*316*	
LCC4	LCC4A	U	236	582	Federal, County/Local, Private/Other.
	LCC4B	U	142	350	Federal, County/Local.
	LCC4C	U	1	3	Private/Other.
	LCC4D	U	7	17	County/Local.
Unit Total			*386*	*952*	
LCC5	LCC5A	U	25	62	State, County/Local, Private/Other.
	LCC5B	U	2	4	County/Local.
	LCC5C	U	7	18	County/Local, Private/Other.
	LCC5D	U	4	10	County/Local.
	LCC5E	U	3	8	County/Local, Private/Other.
	LCC5F	U	29	71	State, County/Local, Private/Other.
	LCC5G	U	4	10	County/Local, Private/Other.
	LCC5H	U	9	22	State, County/Local.
	LCC5I	U	13	31	County/Local, Private/Other.
	LCC5J	U	3	6	Private/Other.
Unit Total			*98*	*242*	
LCC6	LCC6A	U	1	3	Private/Other.
	LCC6B	U	1	1	Private/Other.
	LCC6C	U	1	3	State, Private/Other.
	LCC6D	O	8	19	State, County/Local.
	LCC6E	U	30	74	County/Local, Private/Other.
	LCC6F	U	1	2	Private/Other.
	LCC6G	U	4	9	County/Local, Private/Other.
	LCC6H	U	5	13	County/Local, Private/Other.
	LCC6I	U	<1	1	Private/Other.
	LCC6J	O	2	4	County/Local, Private/Other.
	LCC6K	U	14	35	County/Local, Private/Other.
	LCC6L	U	5	12	County/Local, Private/Other.
	LCC6M	U	4	10	State, County/Local, Private/Other.
	LCC6N	U	13	32	County/Local, Private/Other.
	LCC6O	U	7	17	State, County/Local, Private/Other.
	LCC6P	U	1	3	County/Local, Private/Other.
	LCC6Q	U	1	4	County/Local, Private/Other.
	LCC6R	U	6	15	State, County/Local, Private/Other.
	LCC6S	U	11	28	County/Local, Private/Other.
	LCC6T	U	7	16	County/Local, Private/Other.
	LCC6U	U	6	15	County/Local, Private/Other.
Unit Total			*128*	*315*	
LCC7	LCC7A	U	11	27	County/Local, Private/Other.
	LCC7B	U	4	9	County/Local, Private/Other.
	LCC7C	U	8	20	State, County/Local.
	LCC7D	U	7	18	State, County/Local, Private/Other.
	LCC7E	U	16	39	County/Local, Private/Other.
	LCC7F	U	145	359	State, County/Local, Private/Other.
	LCC7G	U	11	26	State, County/Local, Private/Other.
Unit Total			*201*	*497*	
Total CH			*1,072*	*2,649*	

Note: Area sizes may not sum due to rounding.
[1] Ownership information based on Miami-Dade County parcel data (July 2013) and FNAI's Florida Managed Lands data (March 2014).

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for *Linum carteri* var. *carteri,* below.

Unit LCC1: Trinity Pineland and Surrounding Areas, Miami-Dade County, Florida

Unit LCC1 consists of 19 ac (48 ha) in Miami-Dade County. Within Unit LCC1, there are three subunits—LCC1A and LCC1B (primarily County-owned), and LCC1C (combination of State lands and private ownership). The unit is comprised of State lands within Trinity Pineland County Park (4 ac (10 ha)); County lands primarily within Tropical Park and A. D. ''Doug'' Barnes Park (7 ha (18 ac)); and parcels in private ownership (8 ha (19 ac)). This unit is bordered on the north by SW 24 Street, on the south by the Snapper Creek Expressway (State Road (SR) 878), on the east by SW 67 Avenue, and on the west by SW 87 Avenue. The unit is within the historical range of *Linum carteri* var. *carteri*, although data are lacking regarding historical occupancy of the specific critical habitat patches in the unit. This unit includes the only

remaining pine rockland habitat in this northern portion of the Miami Rock Ridge.

This unit was unoccupied by *Linum carteri* var. *carteri* at the time of listing but is essential to the conservation of the plant because it serves to protect habitat needed to recover the plant, reestablish wild populations within the plant's historical range, and maintain populations throughout the plant's historical distribution in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *L. c.* var. *carteri* be extirpated from one of its current locations.

Unit LCC2: Nixon Smiley Pineland Preserve and Surrounding Areas, Miami-Dade County, Florida

Unit LCC2 consists of approximately 113 ha (278 ac) of habitat in Miami-Dade County. Within Unit LCC2, there are six subunits (LCC2A–LCC2F) comprising primarily conservation lands and including four larger areas plus two smaller areas. The unit is comprised of State lands within Camp Matecumbe, Tamiami Pineland Complex Addition, and Rockdale Pineland (53 ha (131 ac); County/local lands within Nixon Smiley Pineland Preserve, Tamiami #8 (Nixon Smiley Addition) Pineland, Pine Shore Pineland Preserve, Ron Ehman Park, and Rockdale Pineland Addition (59 ha (147 ac)); and parcels in private or other ownership (<1 ha (<1 ac)). This unit is bordered on the north by SW 104 Street, on the south by SW 152 Street (Coral Reef Drive), on the east by U.S. 1 (South Dixie Highway), and on the west by SW 177 Avenue (Krome Avenue).

This unit is composed of both occupied and unoccupied habitat. Some habitat within the unit was occupied by *Linum carteri* var. *carteri* (one occurrence; approximately 16 ha (39 ac)) at the time of listing. This occupied habitat contains some or all of the PCEs, including pine rockland habitat, oolitic limestone substrate, suitable vegetation composition and structure, natural or artificial disturbance regimes, and habitat connectivity of sufficient size and suitability. The PCEs in this unit may require special management considerations or protection to address threats of habitat fragmentation; inadequate fire management; competition with nonnative, invasive plants; and sea level rise. In some cases, these threats are being addressed or coordinated with our partners and landowners to implement needed actions.

Unoccupied habitat within the unit is essential to the conservation of *Linum carteri* var. *carteri* because it serves to protect habitat needed to recover the plant, reestablish wild populations within the plant's historical range, and maintain populations throughout the plant's historical distribution in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *L. c.* var. *carteri* be extirpated from one of its current locations.

Unit LCC3: USDA Subtropical Horticultural Research Station and Surrounding Areas, Miami-Dade County, Florida

Unit LCC3 consists of approximately 128 ha (316 ac) of habitat in Miami-Dade County. Within Unit LCC3, there are nine subunits (LCC3A–LCC3I), including two larger areas (USDA and Deering Estate at Cutler) plus seven smaller areas surrounding these. The unit is comprised of Federal lands within the USDA Subtropical Horticultural Research Station (59 ha (145 ac)); State lands within the R. Hardy Matheson Preserve, Ludlam Pineland, Deering Estate at Cutler, and Deering Estate South Addition (45 ha (112 ac)); County/local lands within Coral Reef Park, Ned Glenn Nature Preserve, and Bill Sadowski Park (15 ha (38 ac)); and parcels in private ownership (8 ha (21 ac)). This unit is bordered on the north by SW 112 Street, on the south by the intersection of Old Cutler Road and Franjo Road (County Road (CR) 977), on the east by the Atlantic Ocean, and on the west by U.S. 1 (South Dixie Highway).

This unit is composed of both occupied and unoccupied habitat. Some habitat within the unit was occupied by *Linum carteri* var. *carteri* (three occurrences; approximately 62 ha (153 ac)) at the time of listing. This occupied habitat contains some or all of the PCEs, including pine rockland habitat, oolitic limestone substrate, suitable vegetation composition and structure, natural or artificial disturbance regimes, and habitat connectivity of sufficient size and suitability. The PCEs in this unit may require special management considerations or protection to address threats of habitat loss and fragmentation; inadequate fire management; competition with nonnative, invasive plants; and sea level rise, including storm surge. In some cases, these threats are being addressed or coordinated with our partners and landowners to implement needed actions.

Unoccupied habitat within the unit is essential to the conservation of *Linum carteri* var. *carteri* because it serves to protect habitat needed to recover the plant, reestablish wild populations within the plant's historical range, and maintain populations throughout the plant's historical distribution in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *L. c.* var. *carteri* be extirpated from one of its current locations.

Unit LCC4: Richmond Pinelands and Surrounding Areas, Miami-Dade County, Florida

Unit LCC4 consists of approximately 386 ha (952 ac) in Miami-Dade County. Within Unit LCC4, there are four subunits (LCC4A–LCC4D), primarily within the Richmond Pinelands complex (made up of Federal and County-owned lands, as well as land owned by the University of Miami). The unit is comprised of Federal lands owned by USCG, ACOE, U.S. Prison Bureau, and NOAA (75 ha (185 ac)); County/local lands within and adjacent to Larry and Penny Thompson Park, Martinez Pineland, Zoo Miami, and Eachus Pineland (240 ha (592 ac)); and parcels in private or other ownership (71 ha (175 ac)). This unit is bordered on the north by SW 152 Street (Coral Reef Drive), on the south by SW 200 St (Quail Drive/SR 994), on the east by U.S. 1 (South Dixie Highway), and on the west by SW 177 Avenue (Krome Avenue).

This unit was unoccupied by *Linum carteri* var. *carteri* at the time of listing but is essential to the conservation of the plant because it serves to protect habitat needed to recover the plant, reestablish wild populations within the plant's historical range, and maintain populations throughout the plant's historical distribution in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *L. c.* var. *carteri* be extirpated from one of its current locations.

Unit LCC5: Quail Roost Pineland and Surrounding Areas, Miami-Dade County, Florida

Unit LCC5 consists of approximately 98 ha (242 ac) in Miami-Dade County. Within Unit LCC5, there are 10 subunits (LCC5A–LCC5J), including 4 larger areas plus 6 smaller areas surrounding these. The unit is comprised of State lands within Quail Roost Pineland, Goulds Pineland and Addition, and Silver Palm Groves Pineland (39 ha (97 ac)); County/local lands including Medsouth Park, Black Creek Forest, Rock Pit #46, and lands owned by the School Board of Miami-Dade County (18 ha (44 ac)); and parcels in private ownership (41 ha (101 ac)), including Porter-Russell Pineland owned by the Tropical Audubon Society. This unit is bordered on the north by SW 200 St (Quail Drive/SR 994), on the south by SW 248 Street, on

the east by the Florida Turnpike, and on the west by SW 194 Avenue.

This unit was unoccupied by *Linum carteri* var. *carteri* at the time of listing but is essential to the conservation of the plant because it serves to protect habitat needed to recover the plant, reestablish wild populations within the plant's historical range, and maintain populations throughout the plant's historical distribution in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *L. c.* var. *carteri* be extirpated from one of its current locations.

Unit LCC6: Camp Owaissa Bauer and Surrounding Areas, Miami-Dade County, Florida

Unit LCC6 consists of approximately 128 ha (315 ac) of habitat in Miami-Dade County. Within Unit LCC6, there are 21 subunits (LCC6A–LCC6U), composed of 1 larger area (Camp Owaissa Bauer and its addition) and 20 smaller areas surrounding it. The unit is comprised of State lands within Owaissa Bauer Pineland Addition, Ingram Pineland, West Biscayne Pineland, and Fuchs Hammock Addition (20 ha (51 ac)); County/local lands including Camp Owaissa Bauer, Pine Island Lake Park, Seminole Wayside Park, and Northrop Pineland (63 ha (156 ac)); and parcels in private ownership (44 ha (109 ac)), including the private conservation area, Pine Ridge Sanctuary. This unit is bordered on the north by SW 248 Street, on the south by SW 312 Street, on the east by SW 112 Avenue, and on the west by SW 217 Avenue.

This unit is composed of both occupied and unoccupied habitat. Some habitat within the unit was occupied by *Linum carteri* var. *carteri* (2 occurrences; approximately 9 ha (23 ac)) at the time of listing. This occupied habitat contains some or all of the PCEs, including pine rockland habitat, oolitic limestone substrate, suitable vegetation composition and structure, natural or artificial disturbance regimes, and habitat connectivity of sufficient size and suitability. The PCEs in this unit may require special management considerations or protection to address threats of habitat loss and fragmentation; inadequate fire management; competition with nonnative, invasive plants; and sea level rise. In some cases, these threats are being addressed or coordinated with our partners and landowners to implement needed actions.

Unoccupied habitat within the unit is essential to the conservation of *Linum carteri* var. *carteri* because it serves to protect habitat needed to recover the plant, reestablish wild populations within the plant's historical range, and maintain populations throughout the plant's historical distribution in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *L. c.* var. *carteri* be extirpated from one of its current locations.

Unit LCC7: Navy Wells Pineland Preserve and Surrounding Areas, Miami-Dade County, Florida

Unit LCC7 consists of approximately 201 ha (497 ac) of habitat in Miami-Dade County. Within Unit LCC7, there are seven subunits (LCC7A–LCC7G), including one larger area (Navy Wells Pineland Preserve) and six smaller outlying areas. The unit is comprised of State lands within Palm Drive Pineland, Navy Wells Pineland #39, Navy Wells Pineland Preserve (portion), and Florida City Pineland (53 ha (132 ac)); County/local lands including primarily Sunny Palms Pineland and Navy Wells Pineland Preserve (portion) (125 ha (309 ac)); and parcels in private ownership (23 ha (56 ac)). This unit is bordered on the north by SW 320 Street, on the south by SW 368 Street, on the east by U.S. 1 (South Dixie Highway), and on the west by SW 217 Avenue.

This unit was unoccupied by *Linum carteri* var. *carteri* at the time of listing but is essential to the conservation of the plant because it serves to protect habitat needed to recover the plant, reestablish wild populations within the plant's historical range, and maintain populations throughout the plant's historical distribution in Miami-Dade County. It also provides habitat for recovery in the case of stochastic events, should *L. c.* var. *carteri* be extirpated from one of its current locations.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

Decisions by the 5th and 9th Circuit Courts of Appeal have invalidated our regulatory definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service,* 378 F. 3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service et al.,* 245 F.3d 434 (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of section 7 consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies sometimes may need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species. Activities that may destroy or adversely modify critical habitat are those that alter the physical or biological features to an extent that appreciably reduces the conservation value of critical habitat for *Brickellia mosieri* and *Linum carteri* var. *carteri.* As discussed above, the role of critical habitat is to support life-history needs of the species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for *Brickellia mosieri* and *Linum carteri* var. *carteri.* These activities include, but are not limited to:

(1) Actions that would significantly alter the pine rockland ecosystem, including significant alterations to hydrology or substrate. Such activities may include, but are not limited to, residential, commercial, or recreational development, including associated infrastructure.

(2) Actions that would significantly alter vegetation structure or composition, such as suppression of natural fires or excessive prescribed burning, or clearing vegetation for construction of residential, commercial, or recreational development and associated infrastructure.

(3) Actions that would introduce nonnative plant species that would significantly alter vegetation structure or composition. Such activities may include, but are not limited to, residential and commercial development, and associated infrastructure.

Exemptions

Application of Section 4(a)(3) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resources management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

(1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;

(2) A statement of goals and priorities;

(3) A detailed description of management actions to be implemented to provide for these ecological needs; and

(4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) now provides: ''The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an INRMP prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.''

We consulted with the military on the development and implementation of INRMPs for installations with listed species. We analyzed INRMPs developed by military installations located within the range of our proposed critical habitat designation for *B. mosieri* and *L. c.* var. *carteri* to determine if they met the criteria for exemption from critical habitat under section 4(a)(3) of the Act. We found that the following areas are Department of Defense lands with completed, Service-approved INRMPs within the range of the proposed critical habitat designation.

Homestead Air Reserve Base—Unit LCC6

The Homestead Air Reserve Base (HARB) has a current and completed INRMP, signed in July 2009. This INRMP identifies goals, objectives, and strategies for the management of HARB's natural resources for a 5-year period (*i.e.,* through 2014), and provides environmental stewardship initiatives for the remaining natural communities on HARB, including pine rocklands, as well as efforts to control invasive and nonnative animal and plant species. The INRMP (including appendices) identifies a ''Remnant Pine Rockland'' management unit (2.1 ha (5.1 ac)), which includes the unoccupied habitat patch proposed for critical habitat designation for *Linum carteri* var. *carteri* (subunit LCC6V; 1.0 ha (2.5 ac)) in the revised proposed rule and availability of the draft economic analysis published in the **Federal Register** on July 15, 2014 (79 FR 41211). The INRMP briefly discusses management recommendations for this area including mechanical reduction of fuel load, herbicide treatment of *Neyraudia reynaudiana* (Burma reed), and potential reforestation of canopy species. The INRMP identifies one objective for the remnant pine rockland: To restore and protect the habitat to support native plant communities and

associated wildlife, including endangered and threatened species' habitat. To achieve this objective, the INRMP proposes the development of a Pine Rockland Restoration and Management Plan (PRRMP) to include invasive and nonnative species removal.

An updated INRMP has been drafted and is expected to be finalized by the time this final critical habitat rule publishes in the **Federal Register** or shortly thereafter. The revised INRMP incorporates the PRRMP, which was finalized in September 2012, as well as a Protected Plant Management Plan (PPMP). The updated INRMP goals include implementation of both plans, which consist of restoring the pine rockland management unit to natural conditions by removing invasive and nonnative plants and animals, reintroducing extirpated native species, preventing pollution, and conducting various maintenance and monitoring procedures. The PPMP is used to supplement and update the INRMP, and currently focuses on measures to manage habitat for *Galactia smallii* (Small's milkpea), *Linum arenicola* (sand flax), and State-protected plant species occurring on HARB. The PPMP states that if *Brickellia mosieri* or *Linum carteri* var. *carteri* are identified on HARB, the PPMP will be revised to include these plants and appropriate management and monitoring activities will be implemented.

The current HARB INRMP benefits *Linum carteri* var. *carteri* through ongoing ecosystem management, which should provide suitable habitat for this plant. Specifically, the PPMP includes control of woody and herbaceous invasive pest plants, which would support suitable habitat for *L. c.* var. *carteri* by helping ensure a more open canopy. In addition, the INRMP includes continued mowing and ''weed whacking,'' which function as a surrogate for periodic fires by reducing competition with weedy species and helping to maintain an open canopy. While these activities are proposed to continue at the current frequencies, weed whacking would be raised to 15 cm (6 in) above the ground to avoid cutting *L. arenicola* too low—this would also benefit *L. c.* var. *carteri,* which has a similar life history and response to mowing, if it were to occur there. (For an indepth discussion related to the effects of invasive, nonnative plants and mowing on *L. c.* var. *carteri,* see *Summary of Factors Affecting the Species* in our proposed listing rule published in the **Federal Register** on October 3, 2013 (78 FR 61273), and as updated in our final listing rule published in the **Federal Register** on September 4, 2014 (79 FR 52567)).

Based on the above considerations, and in accordance with section 4(a)(3)(B)(i) of the Act, we have determined that the identified lands are subject to the HARB INRMP and that conservation efforts identified in the INRMP will provide a benefit to *Linum carteri* var. *carteri.* Therefore, lands within this installation are exempt from critical habitat designation under section 4(a)(3) of the Act. We are not including approximately 1.0 ha (2.5 ac) of habitat in this final critical habitat designation because of this exemption.

Special Operations Command South Headquarters—Units BM6 and LCC6

The U.S. Special Operations Command South Headquarters (SOCSO) has an INRMP that was finalized in December 2014. SOCSO is a 34.1–ha (84.2–ac) property that was formerly part of HARB and is now leased by SOCSO from Miami-Dade County. The SOCSO INRMP provides natural resource management for portions of this property for a 5-year period (2012–2017), focusing on the management of *Galactia smallii* and *Linum arenicola.* In part, the INRMP designates two pine rockland management areas, totaling approximately 7.2 ha (17.9 ac), that will be conserved and managed, including permanent fencing of the areas, invasive plant control, mowing, and prescribed burning. These designated management areas include the unoccupied habitat patches proposed for critical habitat designation for *Brickellia mosieri* (subunit BM6M; 5.2 ha (12.9 ac)) and *Linum carteri* var. *carteri* (subunit LCC6W; totaling 6.0 ha (14.8 ac)) in the revised proposed rule and availability of the draft economic analysis published in the **Federal Register** on July 15, 2014 (79 FR 41211).

The SOCSO INRMP benefits *Brickellia mosieri* and *Linum carteri* var. *carteri* through ongoing ecosystem management, which should provide suitable habitat for these plants. Although conservation benefits and management for *Galactia smallii* and *Linum arenicola* are the focus of the INRMP, some protection and conservation for other native pine rockland plant species (including *B. mosieri* and *L. c.* var. *carteri,* if they were to occur there) will be provided by the use of prescribed fire and invasive species control including herbicide treatments used to benefit *G. smallii* and *L. arenicola.* Prescribed fire is proposed in the management areas on a 4- to 7-year interval, the year following the herbicide treatment if weather conditions permit. In addition, proposed protocols for mowing of the inside perimeter of the management areas would benefit *L. c.* var. *carteri.* Where *G. smallii* and *L. arenicola* occur within the fenced perimeter, winter mowing (mid-January to mid-February) would avoid primary seed set by these species and *L. c.* var. *carteri,* if it were to occur there. In addition, where invasive and nonnative species occur in the mowed area, a broadcast herbicide would be applied to the areas with exotic species approximately 1 month after mowing, further reducing competition and helping to ensure an open canopy.

Based on the above considerations, and in accordance with section 4(a)(3)(B)(i) of the Act, we have determined that the identified lands are subject to the SOCSO INRMP and that conservation efforts identified in the INRMP will provide a benefit to *Brickellia mosieri* and *Linum carteri* var. *carteri.* Therefore, lands within this installation are exempt from critical habitat designation under section 4(a)(3) of the Act. We are not including approximately 6.0 ha (14.8 ac) of habitat in this final critical habitat designation because of this exemption.

Consideration of Impacts Under Section 4(b)(2) of the Act

Under Section 4(b)(2) of the Act, the Secretary may exclude an area from critical habitat if she determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless she determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

Exclusions Based on Economic Impacts

Under section 4(b)(2) of the Act, we must consider the economic impacts of specifying any particular area as critical habitat. In order to consider economic impacts, we prepared an incremental effects memorandum (IEM) and screening analysis (Industrial Economics, Incorporated, 2014) which together with our narrative and interpretation of effects constitute our draft economic analysis (DEA) of the critical habitat designation and related factors. This analysis was made available for public review from July 15, 2014, through August 14, 2014. Following the close of the comment period, we reviewed and evaluated all

information submitted during the comment period that may pertain to our consideration of the probable incremental economic impacts of this critical habitat designation. This information is summarized below and available in the screening analysis for *Brickellia mosieri* and *Linum carteri* var. *carteri* (Industrial Economics, Incorporated, 2014), available at *http://www.regulations.gov*.

In our IEM, we attempted to clarify the distinction between the effects that will result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for *Brickellia mosieri* and *Linum carteri* var. *carteri*'s critical habitat. Because the designations of critical habitat for *B. mosieri* and *L.c.* var. *carteri* were proposed concurrently with the listing, it has been our experience that it is more difficult to discern which conservation efforts are attributable to the species being listed and those which will result solely from the designation of critical habitat. However, the following specific circumstances in this case help to inform our evaluation: (1) The PBFs identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that would result in sufficient harm or harassment to constitute jeopardy to *B. mosieri* and *L. c.* var. *carteri* would also likely adversely affect the essential physical and biological features of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of the designation of critical habitat.

In occupied areas, the economic impacts of implementing the rule through section 7 of the Act will most likely be limited to additional administrative effort to consider adverse modification. This finding is based on the following factors:

- Any activities with a Federal nexus occurring within occupied habitat will be subject to section 7 consultation requirements regardless of critical habitat designation, due to the presence of the listed species; and
- In most cases, project modifications requested to avoid adverse modification are likely to be the same as those needed to avoid jeopardy in occupied habitat.

In unoccupied areas, incremental section 7 costs will include both the administrative costs of consultation and the costs of developing and implementing conservation measures needed to avoid adverse modification of critical habitat. Therefore, this analysis focuses on the likely impacts to activities occurring in unoccupied areas of the critical habitat designation.

This analysis forecasts the total number and administrative cost of future consultations likely to occur for transportation and land management activities undertaken by or funded by Federal agencies within unoccupied habitat. In addition, the analysis forecasts costs associated with conservation efforts that may be recommended in consultation for those activities occurring in unoccupied areas. The total incremental section 7 costs associated with the designation are estimated to be $120,000 (2013 dollars) in a single year for both administrative and conservation effort costs.

The designation of critical habitat is unlikely to trigger additional requirements under State or local regulations. This assumption is based on the protective status currently afforded pine rocklands habitat. Additionally, the designation of critical habitat may cause developers to perceive that private lands will be subject to use restrictions, resulting in perceptional effects. Such costs, if they occur, are unlikely to result in costs reaching $100 million in any one year.

Our economic analysis did not identify any disproportionate costs that are likely to result from the designation. Consequently, the Secretary is not exercising her discretion to exclude any areas from this designation of critical habitat for *Brickellia mosieri* and *Linum carteri* var. *carteri* based on economic impacts.

A copy of the IEM and screening analysis with supporting documents may be obtained by contacting the South Florida Ecological Services Field Office (see **ADDRESSES**) or by downloading from the Internet at *http://www.regulations.gov.*

Exclusions Based on National Security Impacts or Homeland Security Impacts

As discussed above, we have already exempted from the designation of critical habitat under Section 4(a)(3) of the Act those Department of Defense lands with completed INRMPs determined to provide a benefit to *Brickellia mosieri* and *Linum carteri* var. *carteri.* Under section 4(b)(2) of the Act, we consider whether there are other lands where a national security or homeland security impact might exist. In preparing this final rule, we have determined that additional lands within the proposed designation are owned or managed by the Department of Defense and the Department of Homeland Security. However, we anticipate that designation of these additional lands will have no impact on national security or homeland security. Consequently, the Secretary is not intending to exercise her discretion to exclude any areas from this final designation based on impacts on national security or homeland security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we also consider any other relevant impacts resulting from the designation of critical habitat. We consider a number of factors, including whether the landowners have developed any HCPs or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any tribal issues and consider the government-to-government relationship of the United States with tribal entities.

In preparing this final rule, we have determined that there are currently no permitted HCPs or other approved management plans for *Brickellia mosieri* and *Linum carteri* var. *carteri,* and the final designation does not include any tribal lands or tribal trust resources. We anticipate no impact on tribal lands, partnerships, or HCPs from this critical habitat designation. Accordingly, the Secretary is not exercising her discretion to exclude any areas from this final designation based on other relevant impacts.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based

on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

The Service's current understanding of the requirements under the RFA, as amended, and following recent court decisions, is that Federal agencies are only required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself, and therefore, not required to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7 only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies will be directly regulated by this designation. There is no requirement under RFA to evaluate the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities are directly regulated by this rulemaking, the Service certifies that this final critical habitat designation will not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Following our evaluation of the probable incremental economic impacts resulting from the designation of critical habitat for *Brickellia mosieri* and *Linum carteri* var. *carteri,* we affirm the information in our proposed rule concerning E.O. 13211. Specifically, the designation of critical habitat is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule will significantly or uniquely affect

small governments because it will not produce a Federal mandate of $100 million or greater in any year, that is, it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. The economic analysis concludes that incremental impacts may primarily occur due to administrative costs of section 7 consultations for transportation and land management projects; however, these are not expected to significantly affect small governments. Incremental impacts stemming from various species conservation and development control activities are expected to be borne by the Federal Government, State of Florida, and Miami-Dade County, which are not considered small governments. Consequently, we do not believe that the critical habitat designation will significantly or uniquely affect small government entities. As such, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with Executive Order 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), we have analyzed the potential takings implications of designating critical habitat for *Brickellia mosieri* and *Linum carteri* var. *carteri* in a takings implications assessment. As discussed above, the designation of critical habitat affects only Federal actions. Although private parties that receive Federal funding, assistance, or require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. The economic analysis found that no significant economic impacts are likely to result from the designation of critical habitat for *B. mosieri* and *L. c.* var. *carteri.* Because the Act's critical habitat protection requirements apply only to Federal agency actions, few conflicts between critical habitat and private property rights should result from this designation. Based on the best available information, the takings implications assessment concludes that this designation of critical habitat for *B. mosieri* and *L. c.* var. *carteri* does not pose significant takings implications.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this critical habitat designation with, appropriate State resource agencies in Florida. We did not receive comments from the State of Florida. We note, however, that one peer reviewer was from the Florida Forest Service, Florida Department of Agriculture and Consumer Services, and we have addressed those comments in the Summary of Comments and Recommendations section of this rule. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the rule does not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical and biological features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist these local governments in long-range planning (because these local governments no longer have to wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the applicable standards set forth in sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of these plants, the rule identifies the elements of physical or biological features essential to the conservation of *Brickellia mosieri* and *Linum carteri* var. *carteri.* The designated areas of critical habitat are presented on maps, and the rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

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

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that

tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

We have determined that there are no tribal lands occupied by *Brickellia mosieri* or *Linum carteri* var. *carteri* at the time of listing that contain the physical or biological features essential to conservation of the species, and no tribal lands unoccupied by *B. mosieri* or *L. c.* var. *carteri* that are essential for the conservation of the species. Therefore, we are not designating critical habitat for *B. mosieri* or *L. c.* var. *carteri* on tribal lands.

References Cited

A complete list of all references cited is available on the Internet at *http://www.regulations.gov* and upon request from the South Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this rulemaking are the staff members of the South Florida Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

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

Regulation Promulgation

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

PART 17—[AMENDED]

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

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

■ 2. Amend § 17.12(h) by revising the entries for ''*Brickellia mosieri''* and ''*Linum carteri* var. *carteri''* under FLOWERING PLANTS in the List of Endangered and Threatened Plants to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
Flowering Plants							
*	*	*	*	*	*	*	
Brickellia mosieri	Florida brickell-bush	U.S.A. (FL)	Asteraceae	E	844	17.96(a)	NA
*	*	*	*	*	*	*	
Linum carteri var. *carteri*.	Carter's small-flowered flax.	U.S.A. (FL)	Linaceae	E	844	17.96(a)	NA
*	*	*	*	*	*	*	

* * * * *

■ 3. In § 17.96, amend paragraph (a) as follows:

■ a. By adding an entry for ''*Brickellia mosieri* (Florida brickell-bush)'' in alphabetical order under the family Asteraceae;

■ b. By adding Family Linaceae in alphabetical order to the list of families; and

■ c. By adding an entry for ''*Linum carteri* var. *carteri* (Carter's small-flowered flax)'' in alphabetical order under the family Linaceae.

The additions read as follows:

§ 17.96 Critical habitat—plants.

(a) *Flowering plants.*

* * * * *

Family Asteraceae: *Brickellia mosieri* (Florida brickell-bush)

(1) Critical habitat units for *Brickellia mosieri* are depicted for Miami-Dade County, Florida, on the maps in this entry.

(2) Within these areas, the primary constituent elements of the physical or biological features essential to the conservation of *Brickellia mosieri* are:

(i) Areas of pine rockland habitat that contain:

(A) Open canopy, semi-open subcanopy, and understory;

(B) Substrate of oolitic limestone rock; and

(C) A plant community of predominately native vegetation that may include, but is not limited to:

(1) Canopy vegetation dominated by *Pinus elliottii* var. *densa* (South Florida slash pine);

(2) Subcanopy vegetation that may include, but is not limited to, *Serenoa repens* (saw palmetto), *Sabal palmetto* (cabbage palm), *Coccothrinax argentata* (silver palm), *Myrica cerifera* (wax myrtle), *Myrsine floridana* (myrsine), *Metopium toxiferum* (poisonwood), *Byrsonima lucida* (locustberry), *Tetrazygia bicolor* (tetrazygia), *Guettarda scabra* (rough velvetseed), *Ardisia escallonioides* (marlberry), *Psidium longipes* (mangroveberry), *Sideroxylon salicifolium* (willow bustic), and *Rhus copallinum* (winged sumac);

(3) Short-statured shrubs that may include, but are not limited to, *Quercus pumila* (running oak), *Randia aculeata* (white indigoberry), *Crossopetalum ilicifolium* (Christmas berry), *Morinda royoc* (redgal), and *Chiococca alba* (snowberry); and

(4) Understory vegetation that may include, but is not limited to: *Andropogon* spp.; *Schizachyrium gracile, S. rhizomatum,* and *S. sanguineum* (bluestems); *Aristida purpurascens* (arrowfeather threeawn); *Sorghastrum secundum* (lopsided Indiangrass); *Muhlenbergia capillaris* (hairawn muhly); *Rhynchospora floridensis* (Florida white-top sedge); *Tragia saxicola* (pineland noseburn); *Echites umbellata* (devil's potato); *Croton linearis* (pineland croton); *Chamaesyce* spp. (sandmats); *Chamaecrista deeringiania* (partridge pea); *Zamia integrifolia* (coontie); and *Anemia adiantifolia* (maidenhair pineland fern).

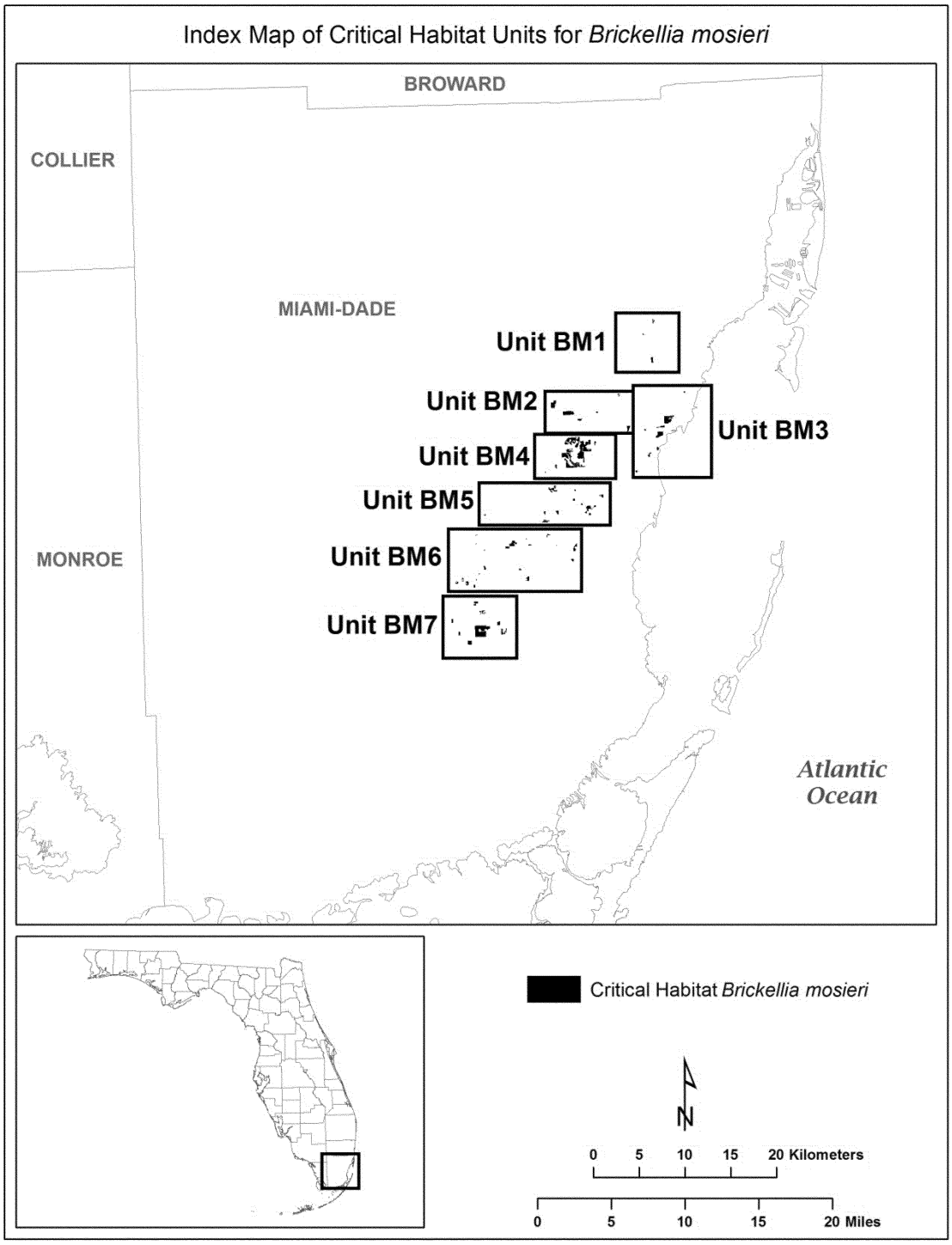
(ii) A disturbance regime that naturally or artificially duplicates natural ecological processes (*e.g.,* fire, hurricanes, or other weather events) and that maintains the pine rockland habitat described in paragraph (2)(i) of this entry.

(iii) Habitats that are connected and of sufficient area to sustain viable populations of *Brickellia mosieri* in the pine rockland habitat described in paragraph (2)(i) of this entry.

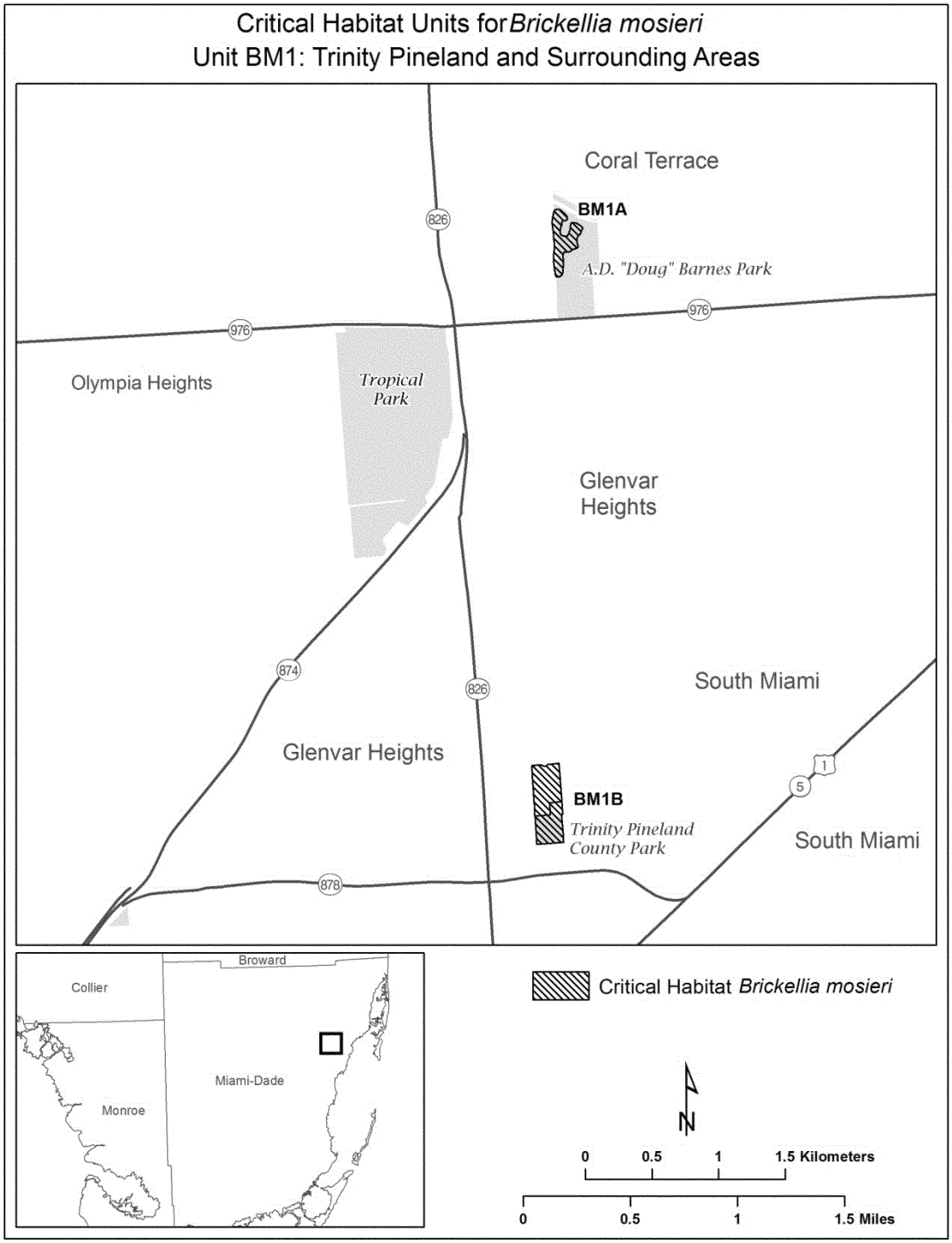
(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located exists within the legal boundaries on September 16, 2015.

(5) Critical habitat map units. Unit maps were developed using ESRI ArcGIS mapping software along with various spatial data layers. ArcGIS was also used to calculate the size of habitat areas. The projection used in mapping and calculating distances and locations within the units was North American Albers Equal Area Conic, NAD 83. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's Internet site at *http://www.fws.gov/verobeach/,* at the Federal eRulemaking Portal (*http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0108), and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

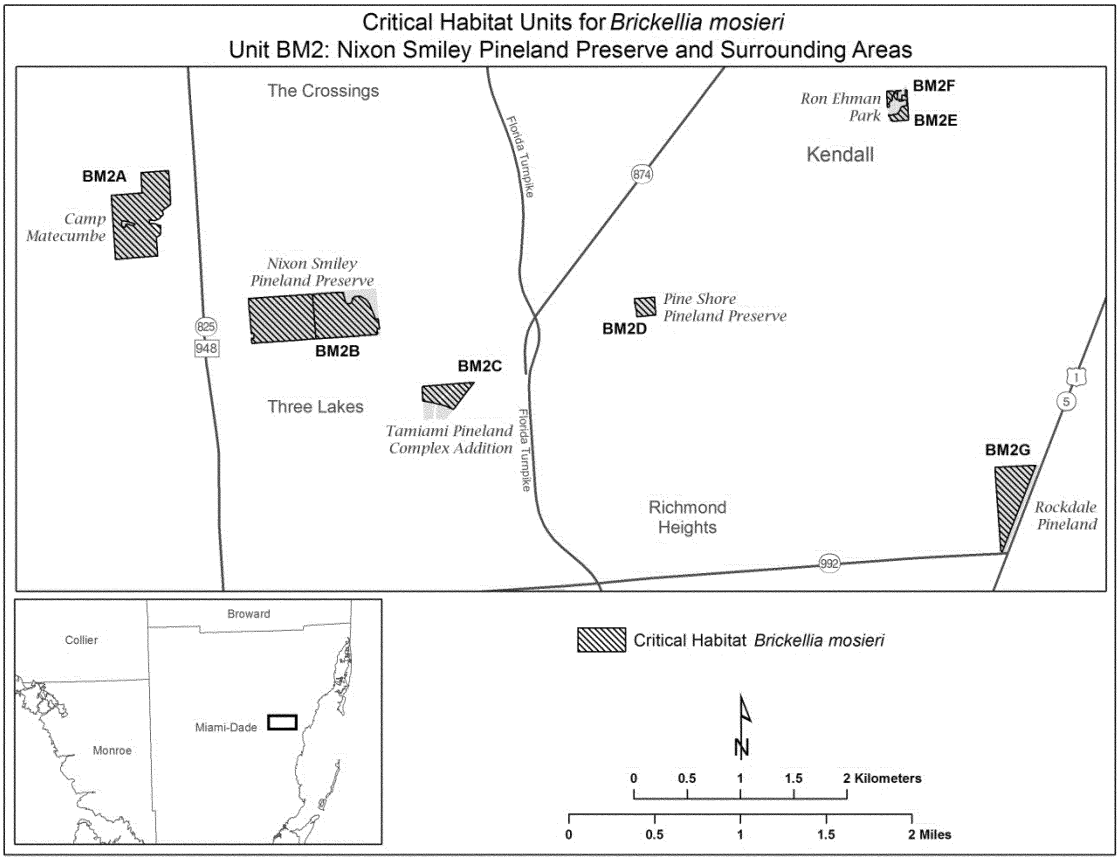
(5) Index map follows:



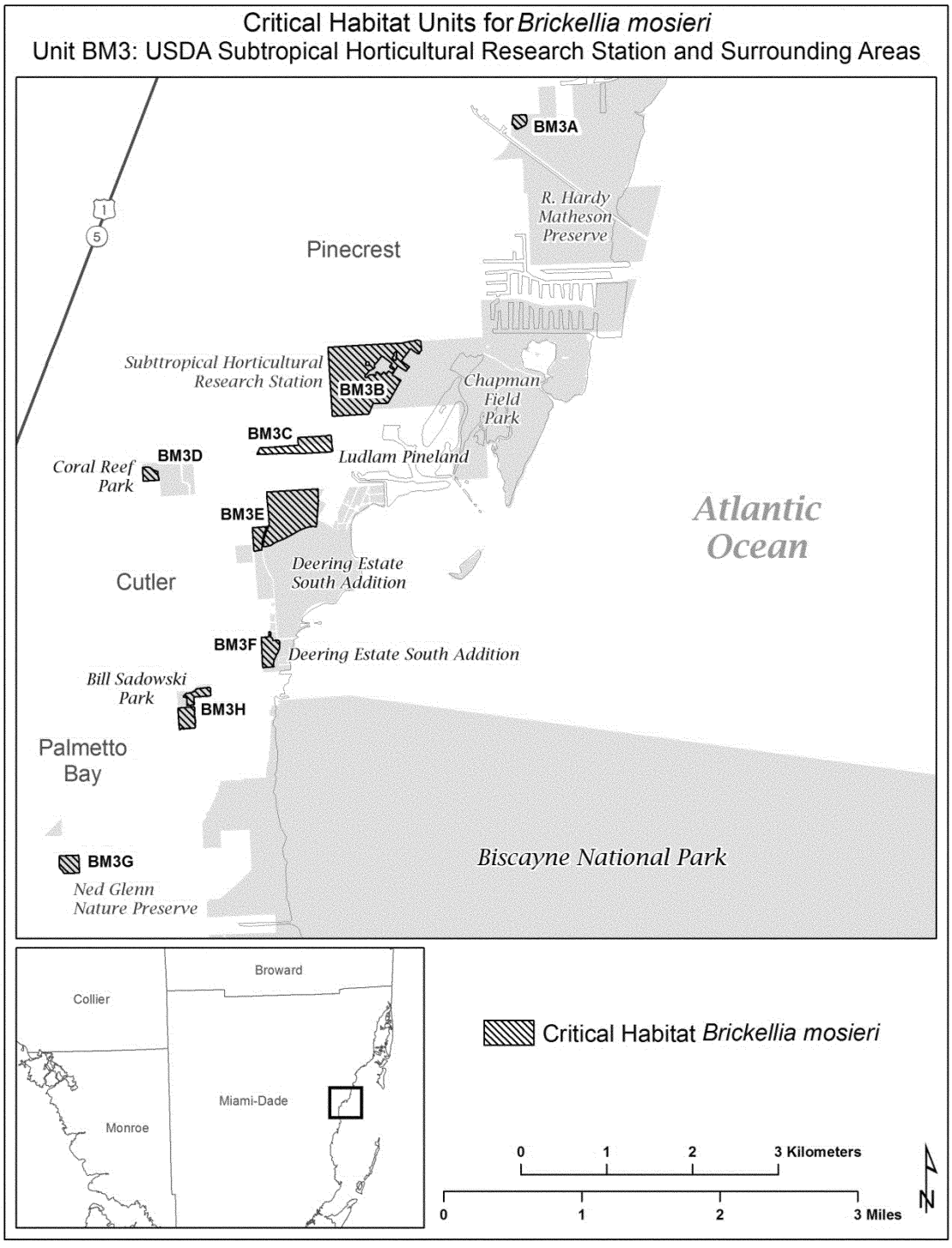
(6) Unit BM1: Trinity Pineland and surrounding areas, Miami-Dade County, Florida. Map of Unit BM1 follows:



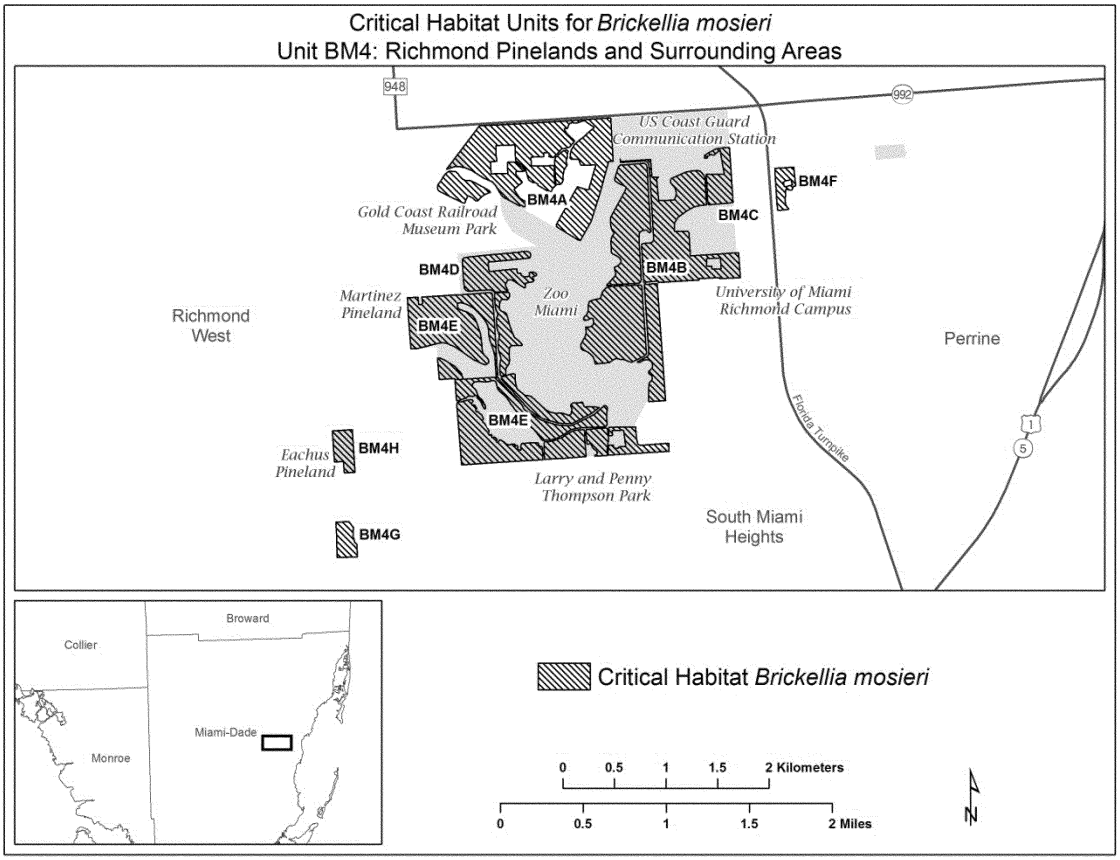
(7) Unit BM2: Nixon Smiley Pineland Preserve and surrounding areas, Miami-Dade County, Florida. Map of Unit BM2 follows:



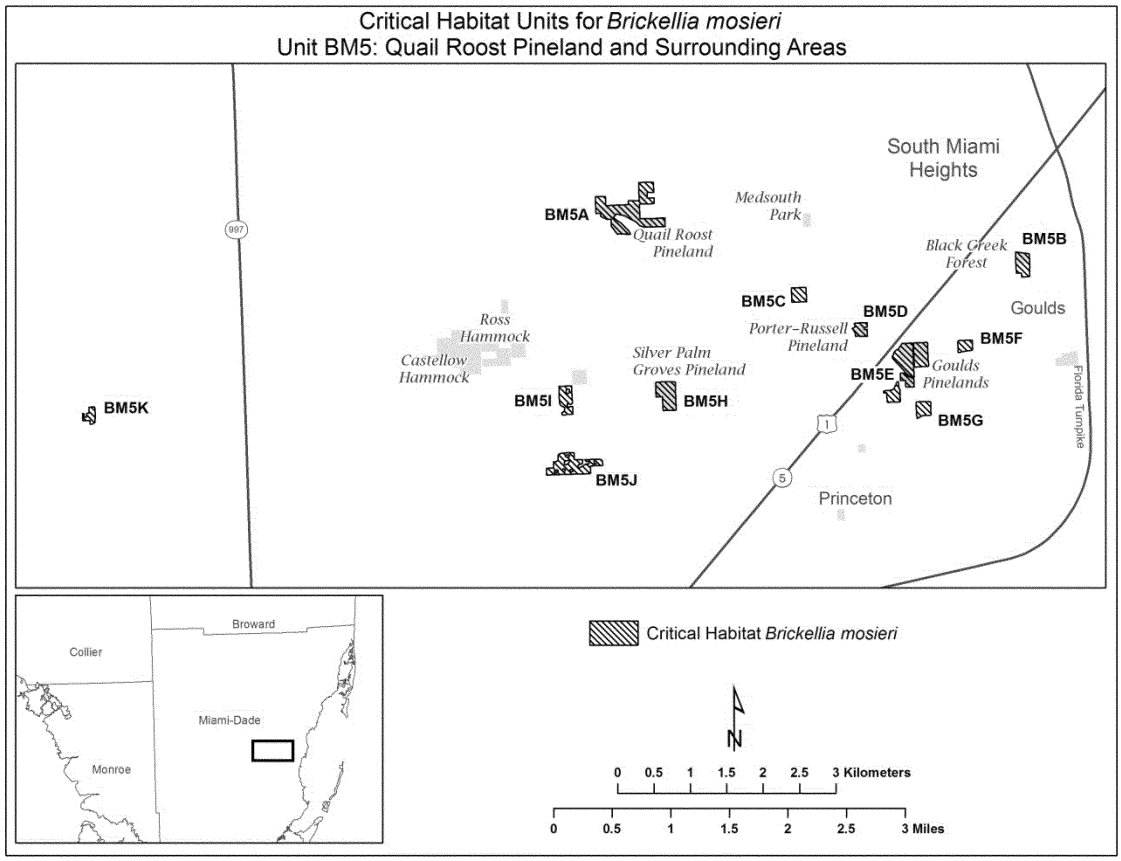
(8) Unit BM3: USDA Subtropical Horticultural Research Station and surrounding areas, Miami-Dade County, Florida. Map of Unit BM3 follows:



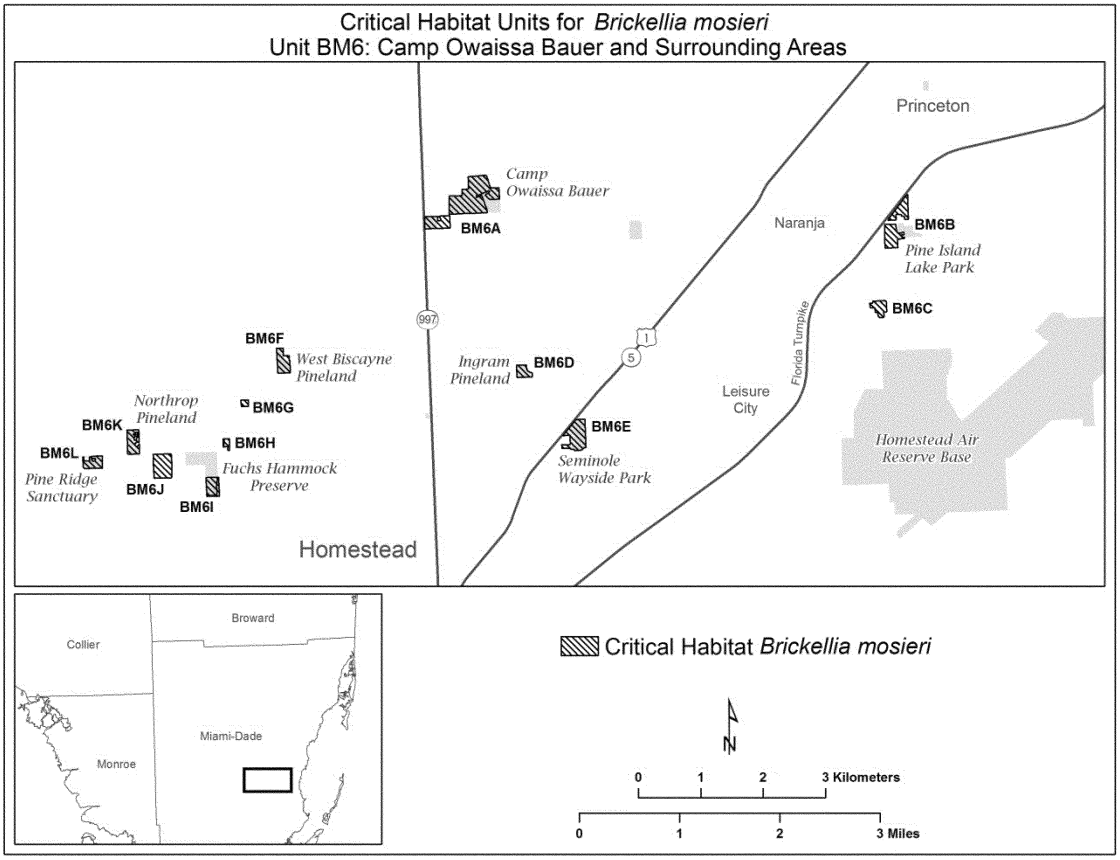
(9) Unit BM4: Richmond Pinelands and surrounding areas, Miami-Dade County, Florida. Map of Unit BM4 follows:



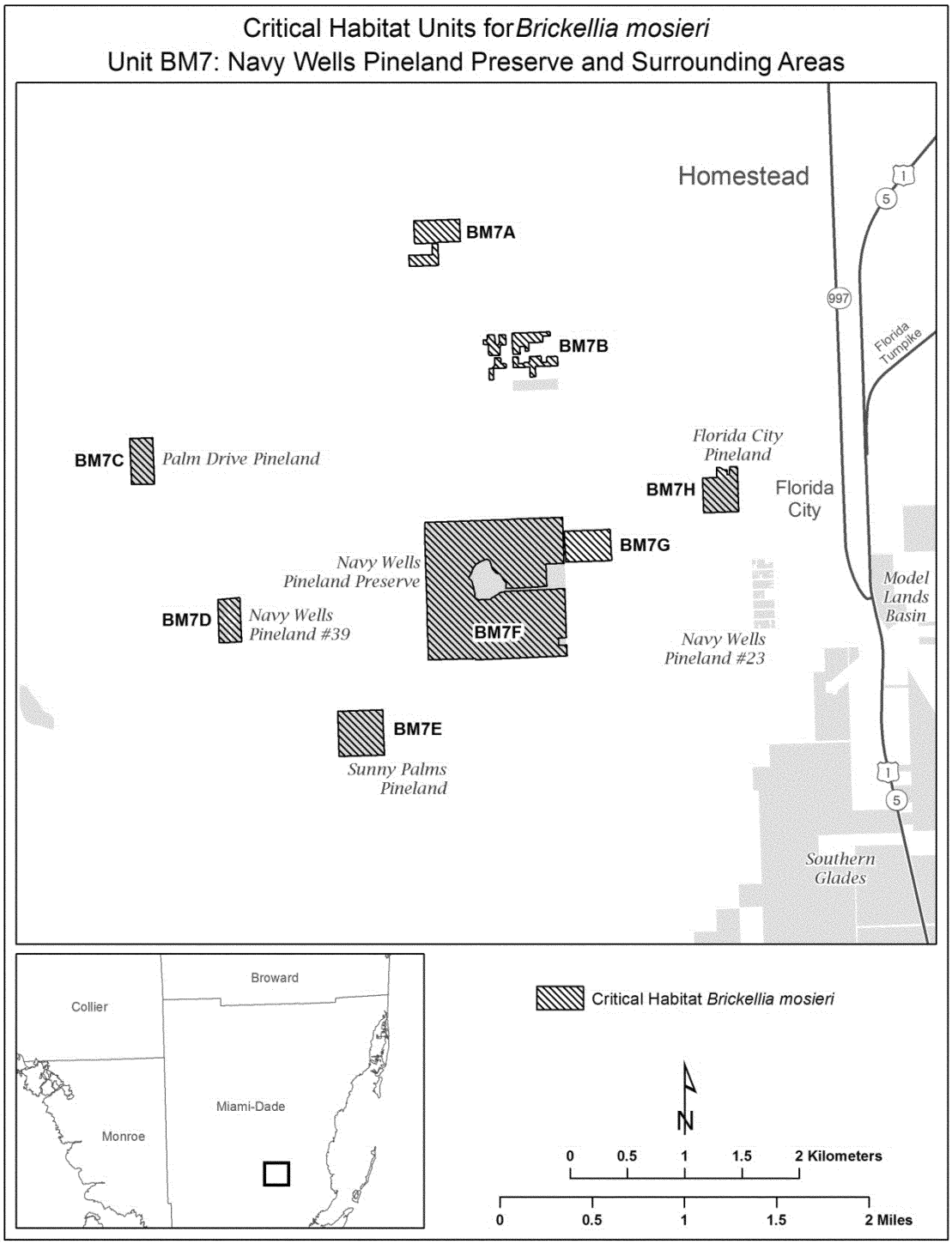
(10) Unit BM5: Quail Roost Pineland and surrounding areas, Miami-Dade County, Florida. Map of Unit BM5 follows:



(11) Unit BM6: Camp Owaissa Bauer and surrounding areas, Miami-Dade County, Florida. Map of Unit BM6 follows:



(12) Unit BM7: Navy Wells Pineland Preserve and surrounding areas, Miami-Dade County, Florida. Map of Unit BM7 follows:



* * * * *

Family Linaceae: *Linum carteri* var. *carteri* (Carter's small-flowered flax)

(1) Critical habitat units for *Linum carteri* var. *carteri* are depicted for Miami-Dade County, Florida, on the maps in this entry.

(2) Within these areas, the primary constituent elements of the physical or biological features essential to the conservation of *Linum carteri* var. *carteri* are:

(i) Areas of pine rockland habitat that contain:

(A) Open canopy, semi-open subcanopy, and understory;

(B) Substrate of oolitic limestone rock; and

(C) A plant community of predominately native vegetation that may include, but is not limited to:

(1) Canopy vegetation dominated by *Pinus elliottii* var. *densa* (South Florida slash pine);

(2) Subcanopy vegetation that may include, but is not limited to, *Serenoa repens* (saw palmetto), *Sabal palmetto* (cabbage palm), *Coccothrinax argentata* (silver palm), *Myrica cerifera* (wax myrtle), *Myrsine floridana* (myrsine), *Metopium toxiferum* (poisonwood), *Byrsonima lucida* (locustberry), *Tetrazygia bicolor* (tetrazygia), *Guettarda scabra* (rough velvetseed), *Ardisia escallonioides* (marlberry), *Psidium longipes* (mangroveberry), *Sideroxylon salicifolium* (willow bustic), and *Rhus copallinum* (winged sumac);

(3) Short-statured shrubs that may include, but are not limited to, *Quercus pumila* (running oak), *Randia aculeata* (white indigoberry), *Crossopetalum ilicifolium* (Christmas berry), *Morinda royoc* (redgal), and *Chiococca alba* (snowberry); and

(4) Understory vegetation that may include, but is not limited to: *Andropogon* spp.; *Schizachyrium gracile, S. rhizomatum,* and *S. sanguineum* (bluestems); *Aristida purpurascens* (arrowfeather threeawn); *Sorghastrum secundum* (lopsided Indiangrass); *Muhlenbergia capillaris* (hairawn muhly); *Rhynchospora floridensis* (Florida white-top sedge); *Tragia saxicola* (pineland noseburn); *Echites umbellata* (devil's potato); *Croton linearis* (pineland croton); *Chamaesyce* spp. (sandmats); *Chamaecrista deeringiania* (partridge pea); *Zamia integrifolia* (coontie); and *Anemia adiantifolia* (maidenhair pineland fern).

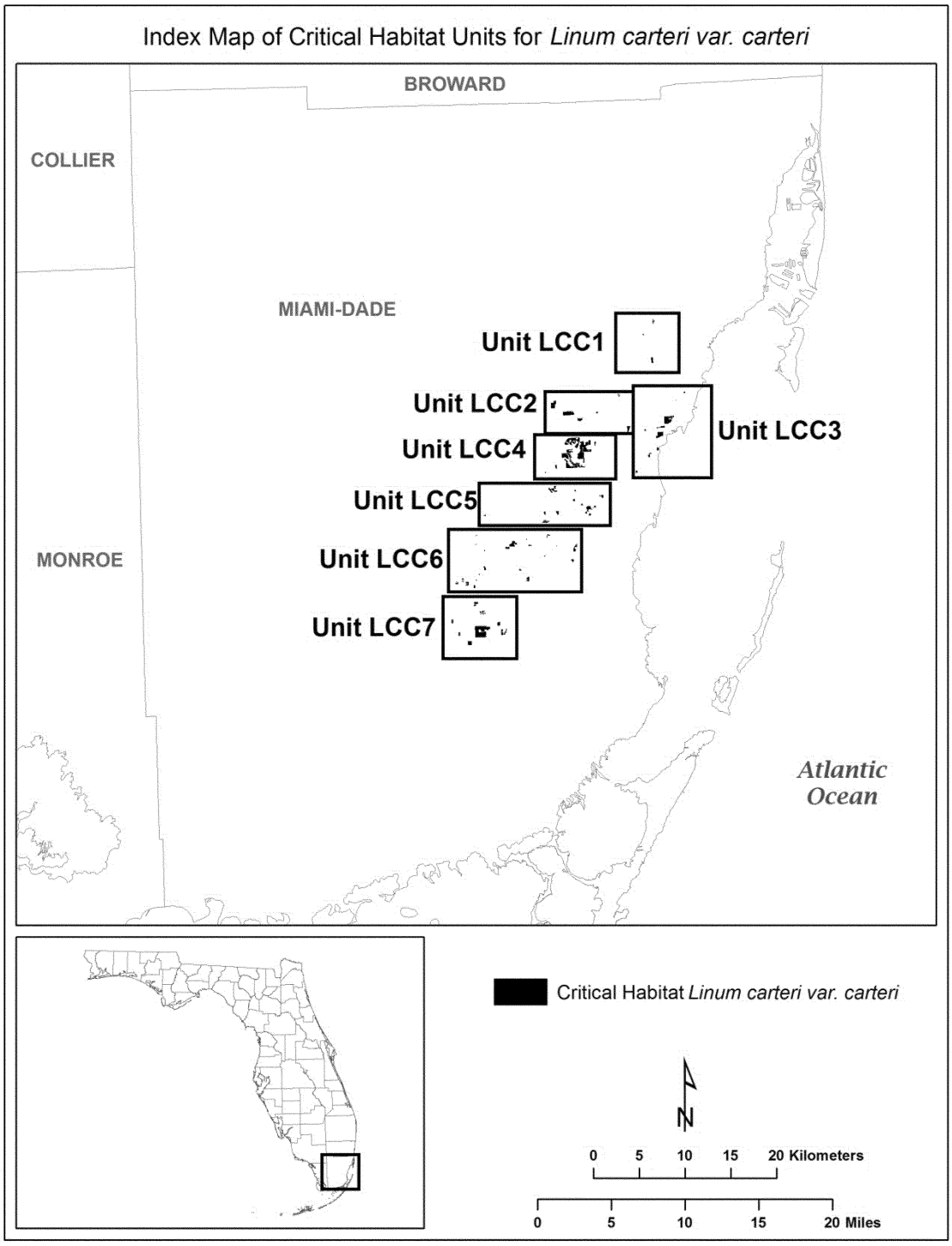
(ii) A disturbance regime that naturally or artificially duplicates natural ecological processes (*e.g.,* fire, hurricanes, or other weather events) and that maintains the pine rockland habitat described in paragraph (2)(i) of this entry.

(iii) Habitats that are connected and of sufficient area to sustain viable populations of *Linum carteri* var. *carteri* in the pine rockland habitat described in paragraph (2)(i) of this entry.

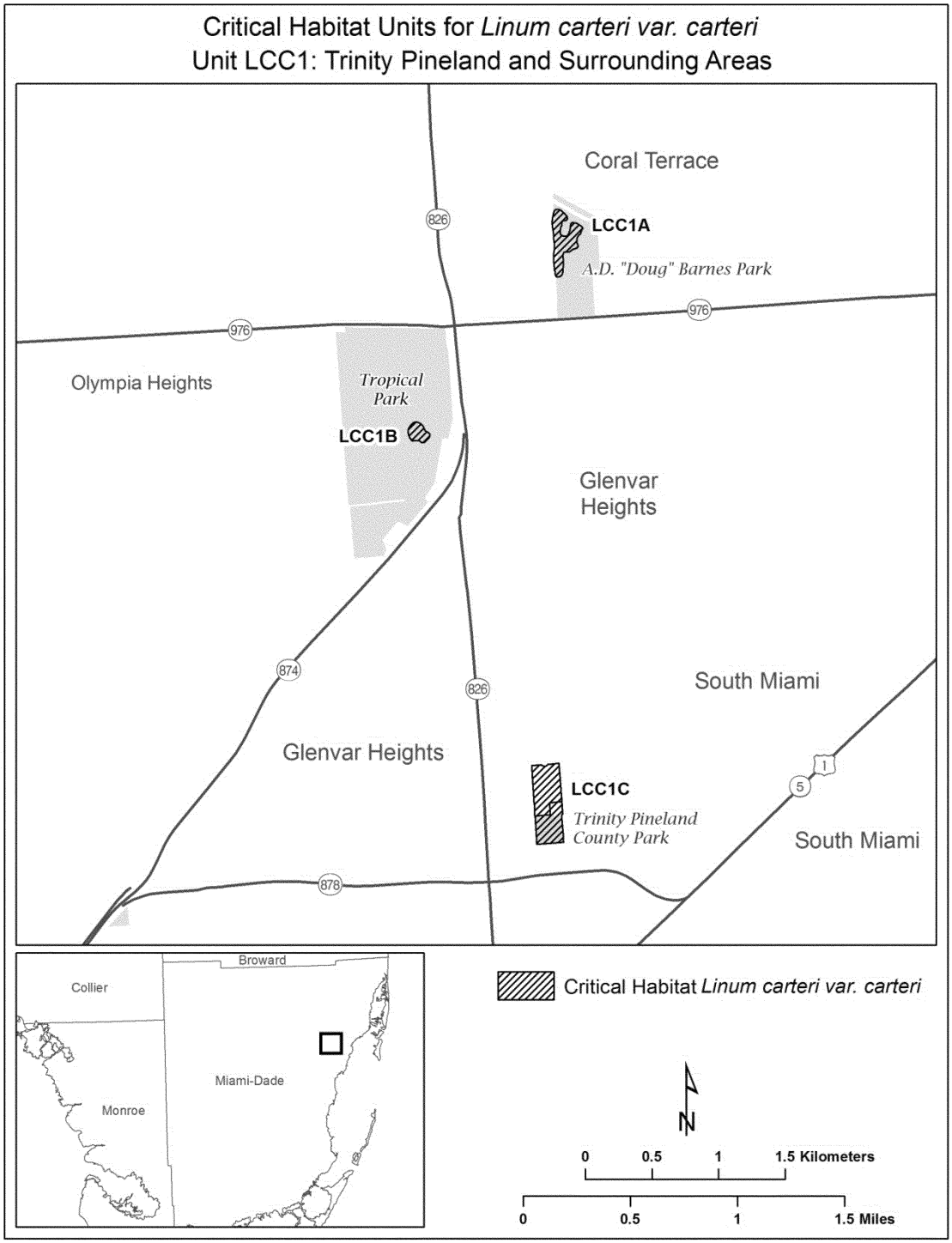
(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located exists within the legal boundaries on September 16, 2015.

(4) *Critical habitat map units.* Unit maps were developed using ESRI ArcGIS mapping software along with various spatial data layers. ArcGIS was also used to calculate the size of habitat areas. The projection used in mapping and calculating distances and locations within the units was North American Albers Equal Area Conic, NAD 83. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's Internet site at *http://www.fws.gov/verobeach/,* at the Federal eRulemaking Portal (*http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0108), and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

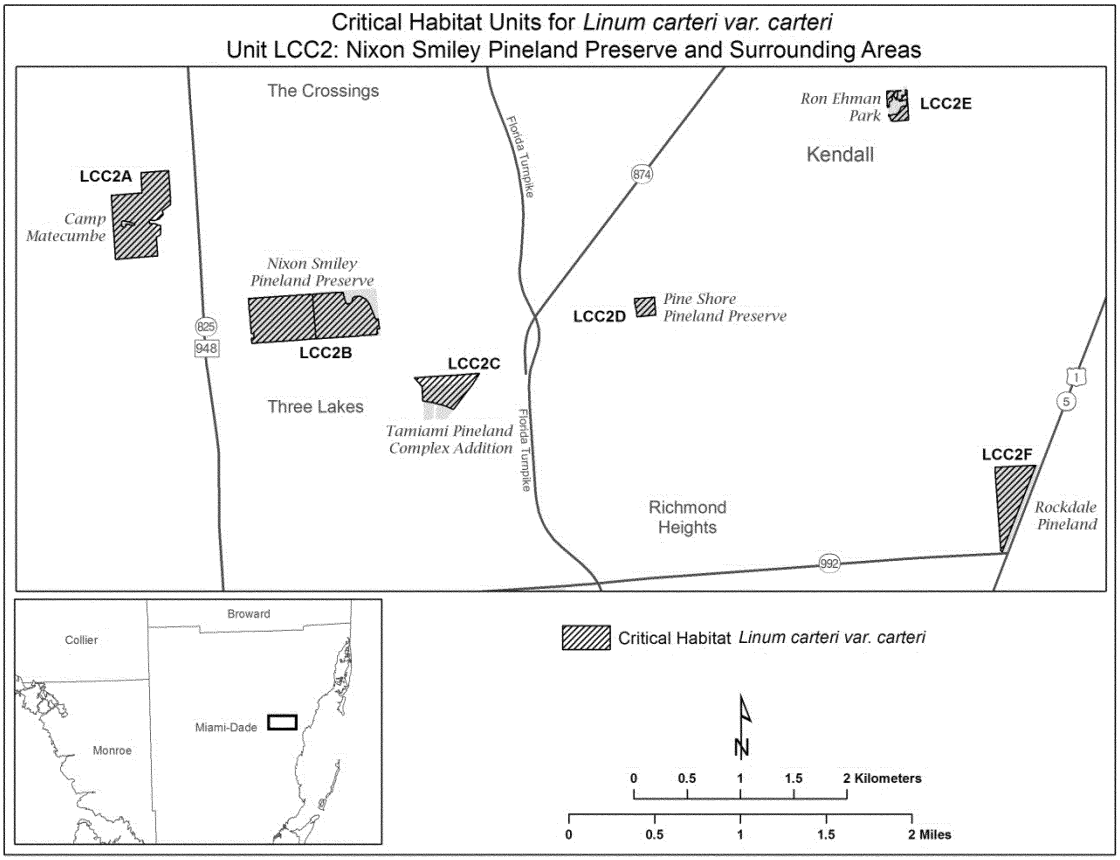
(5) Index map follows:



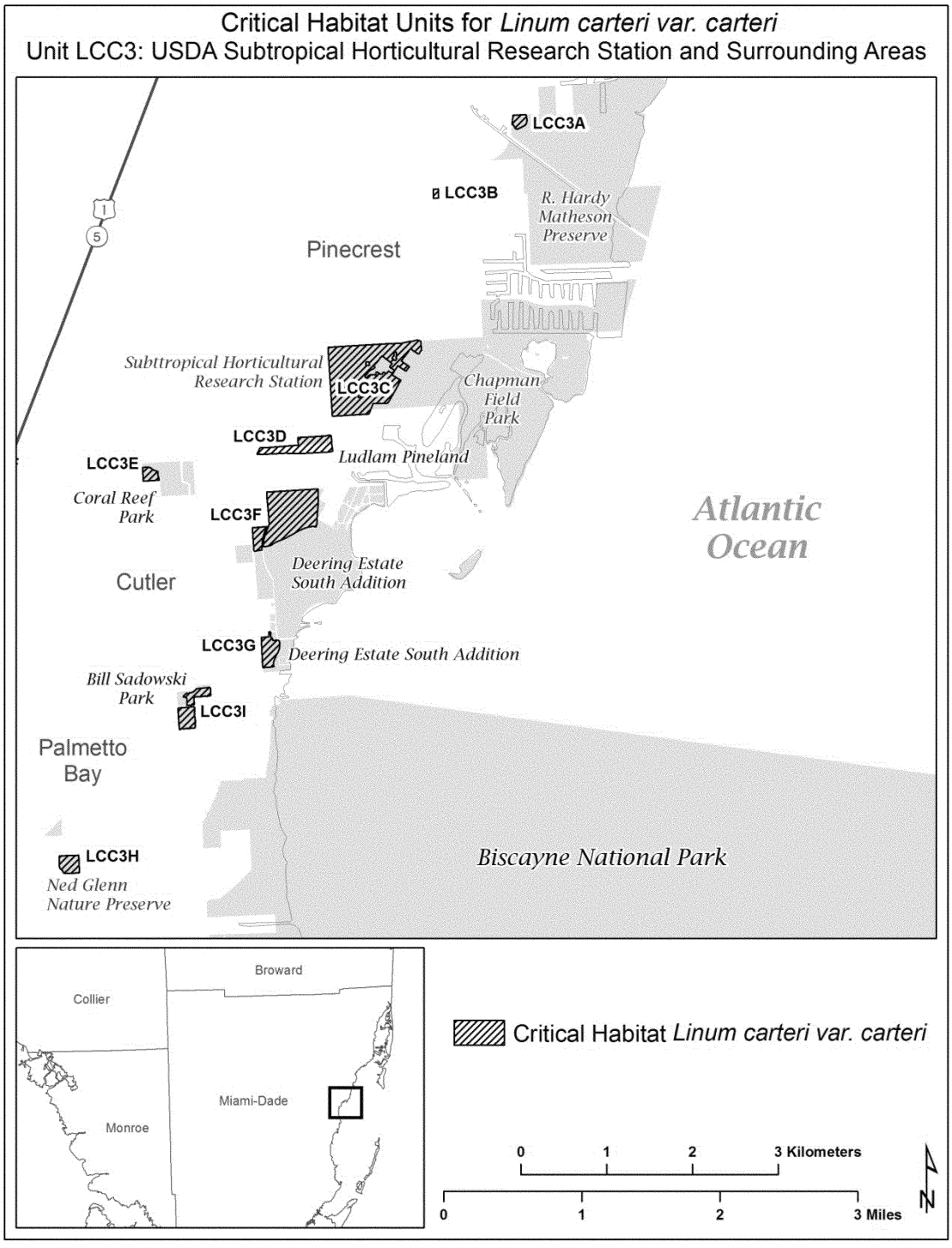
(6) Unit LCC1: Trinity Pineland and surrounding areas, Miami-Dade County, Florida. Map of Unit LCC1 follows:



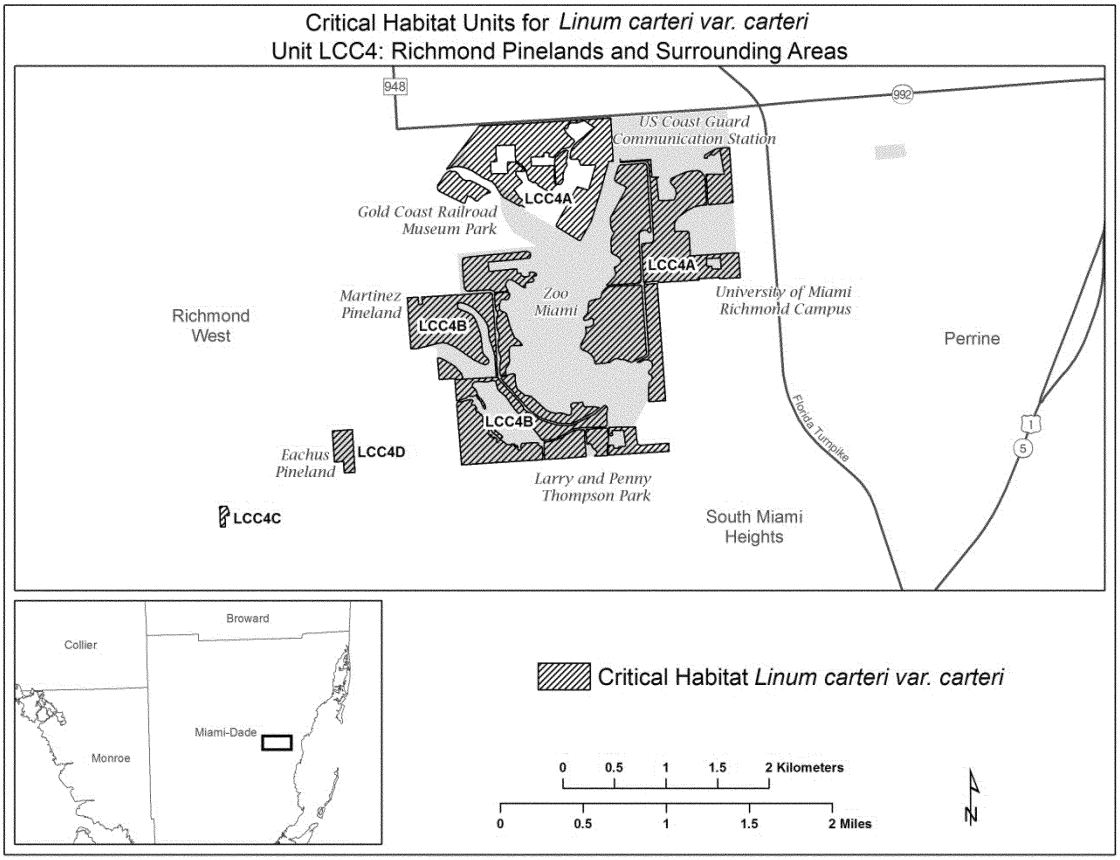
(7) Unit LCC2: Nixon Smiley Pineland Preserve and surrounding areas, Miami-Dade County, Florida. Map of Unit LCC2 follows:



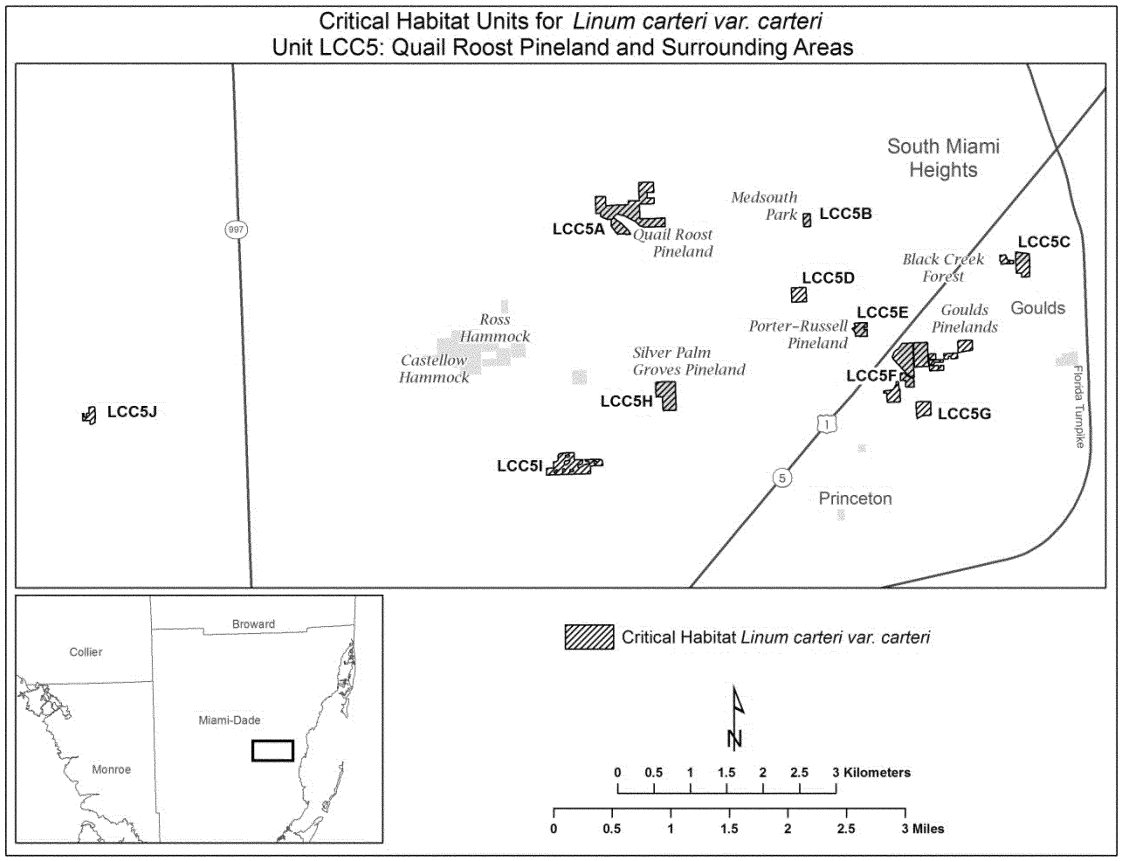
(8) Unit LCC3: USDA Subtropical Horticultural Research Station and surrounding areas, Miami-Dade County, Florida. Map of Unit LCC3 follows:



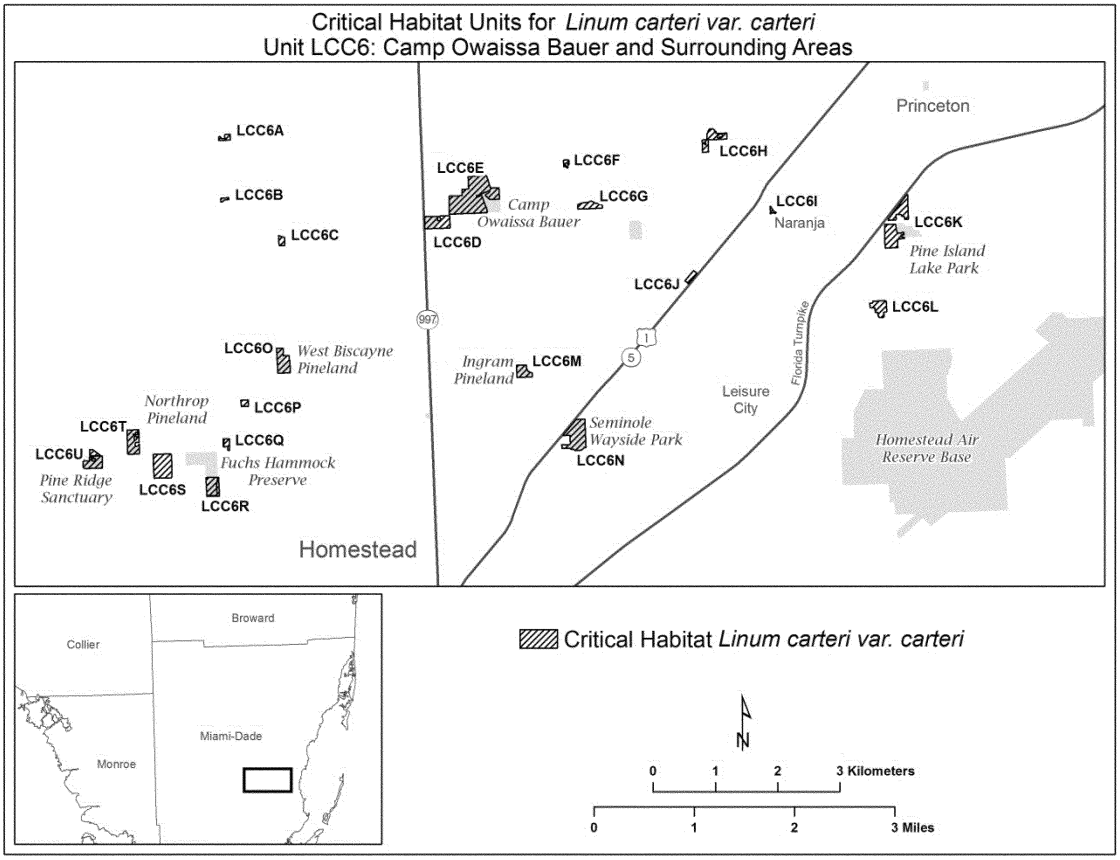
(9) Unit LCC4: Richmond Pinelands and surrounding areas, Miami-Dade County, Florida. Map of Unit LCC4 follows:



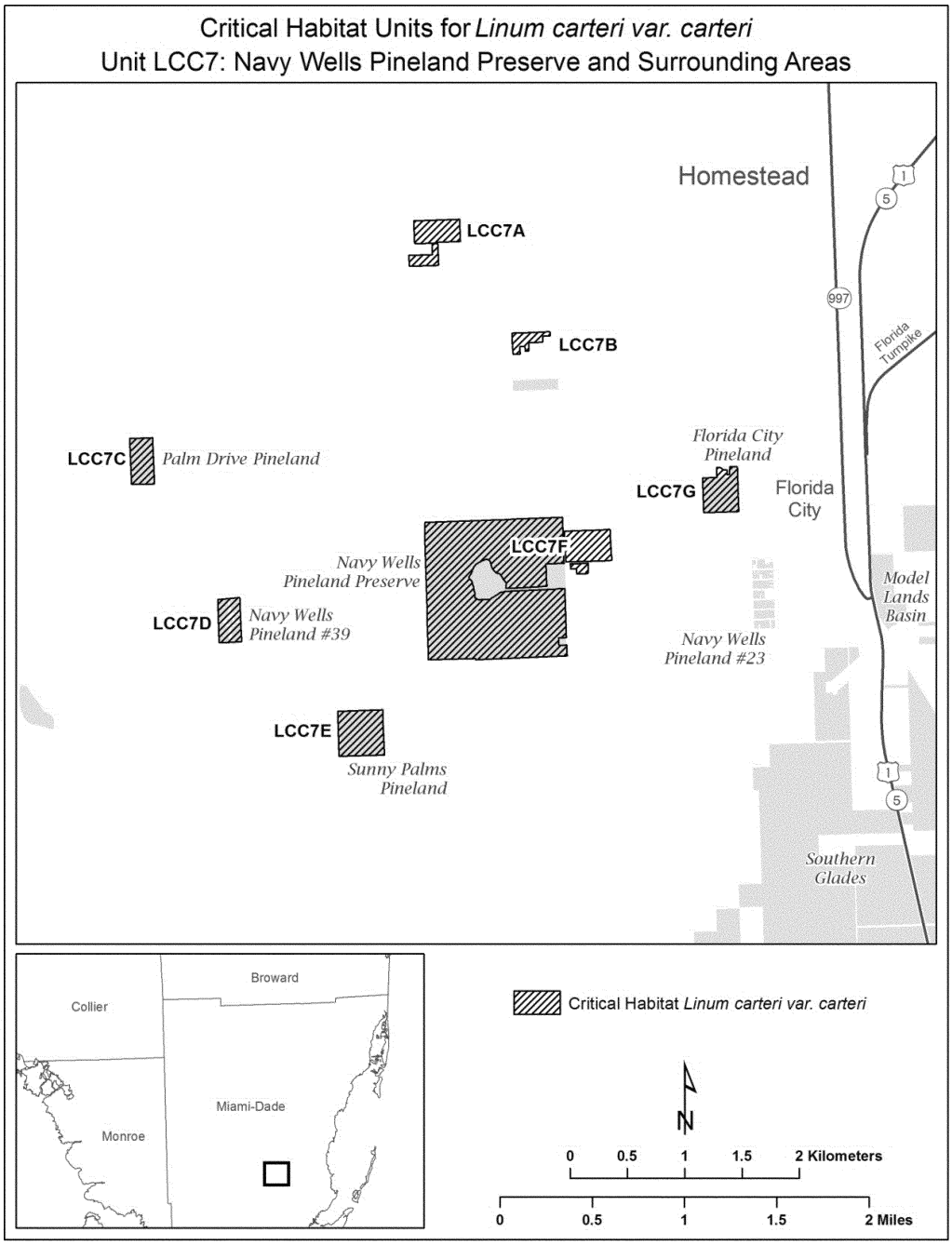
(10) Unit LCC5: Quail Roost Pineland and surrounding areas, Miami-Dade County, Florida. Map of Unit LCC5 follows:



(11) Unit LCC6: Camp Owaissa Bauer and surrounding areas, Miami-Dade County, Florida. Map of Unit LCC6 follows:



(12) Unit LCC7: Navy Wells Pineland Preserve and surrounding areas, Miami-Dade County, Florida. Map of Unit LCC7 follows:



* * * * *

Dated: July 16, 2015.

Michael Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2015–19533 Filed 8–14–15; 8:45 am]

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